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NIH Guide for Grants and Contracts

Vol. 13, No. 7, May 25, 1984

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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MAY 25 1984

National Institutes of Health

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

REVISED SALARY CEILING FOR RESEARCH CAREER
MANPOWER DEVELOPMENT PROGRAMS

P.T. 34; K.W. 1014002

This notice contains information on NIH plans to permit an increase in the amount of salary that may be requested on the following awards in the Research Career Manpower Development series:

- Academic/Teacher Investigator Award (K07)
- Clinical Investigator Award (K08)
- Mid-Career Award (K07)
- Physician Scientist Award (K11, K12)
- Research Career Development Award (K04)
- Special Emphasis Research Career Award (K01)

Beginning with awards made from FY 1985 funds (competing and non-competing awards made on or after October 1, 1984), requests for base salaries up to \$40,000 a year plus applicable fringe benefits will be considered.

Proposed salary levels must be in accordance with institutional salary levels, consistently applied, regardless of the source of support. Justification for the sum requested must include a comparison of the salaries of other individuals at the applicant institution of equivalent rank and experience to that of the awardee. In the case of the Physician Scientist Award Phase I, the comparison group is the house staff training level at which the applicant would be if he/she were on a residency track. In Phase II, the salary may be compared to that of junior faculty with similar training and experience.

NOTICE

DISPLAY OF INDIRECT COSTS ON NOTICES OF GRANT AWARD

P.T. 34, 44; K.W. 1014002

Each NIH Notice of Grant Award issued on or after July 1, 1984, will include the dollar amount of indirect costs expected to be provided in association with that grant. This amount will be identified in the "Remarks" section as follows:

Indirect costs for this award are expected to be
\$ _____. Actual indirect costs will be
provided on a Summary Notice.

In all other respects the system that NIH has followed since July 1971 for issuing, adjusting and settling indirect costs applicable to research project grants will continue to be followed.

While the indirect cost amount to be displayed on each Notice of Grant Award is an early indication of the indirect cost allowance expected to be provided via the usual Summary Notice (Summary Listing of Indirect Cost Awarded/Adjusted), grantee institutions should continue to use the latter document for posting actual allowances to their accounting records and as a source for identifying subsequent post-award indirect cost adjustments.

Questions applicable to the Summary Notice should continue to be addressed to:

National Institutes of Health
Division of Financial Management
Federal Assistance Accounting Branch
Accounting and Indirect Cost Section
Building 31 - Room B1B05
Bethesda, Maryland 20205

Telephone: (301) 496-5315

NOTICE

ADDENDUM TO PHS GRANTS POLICY STATEMENT

P.T. 34, 44; K.W. 1014002

An Addendum to the Public Health Service Grants Policy Statement has just been issued and is generally effective for grants with budget periods beginning on or after April 1, 1984; however, select additional authorities described in the document have been extended to the Institutional Prior Approval System for grants active on April 1, 1984 regardless of the budget period beginning date.

The Public Health Service (PHS) has sent one copy of the Addendum to each PHS grantee institution of record. A limited number of additional copies may be obtained by sending a written request to the following office:

Grants Management Branch
Division of Grants and Contracts
ORM/OM/PHS
5600 Fishers Lane
Rockville, Maryland 20857

In the interest of facilitating broad communication of the changes as expeditiously as possible, the Addendum is reprinted in its entirety (including the cover) at the end of this Guide. Please feel free to make whatever number of photocopies of the reprint you see fit.

NOTICE

A CONTRACTOR'S RESPONSIBILITIES UNDER THE "LIMITATION OF COST" (OR FUNDS) CLAUSE

P.T. 34, 14; K.W. 1014002

NATIONAL INSTITUTES OF HEALTH

The purpose of this notice is to emphasize responsibilities of contractors under the "Limitation of Cost" Clause in cost-reimbursement contracts, and the "Limitation of Funds" Clause in incrementally funded contracts. These clauses require a contractor to notify the contracting officer in writing whenever it has reason to believe that actual costs of performance are expected to be greater or less than the estimated cost or amount funded. A contractor may not make expenditures beyond that limit except at its own risk.

When entering into a cost-reimbursement contract, the contractor assumes responsibility for maintaining an accounting system adequate to alert the contractor of the possibility of a cost overrun before the overrun is incurred. The contractor also assumes a responsibility of informing the contracting officer when the contract funds are nearing exhaustion with an estimate of how much is needed to complete the contract. The contractor is under no duty to continue performance after incurring costs up to the current contract amount.

Timely written notice under the appropriate clause enables the contracting officer to elect whether to add funds in time to prevent interruption of the work or to phase out the work where additional funds are unavailable or unjustified. Thus, even if a cost-reimbursement contractor gives proper notice of an overrun, it would not be entitled to further reimbursement unless authorized by the contracting officer in writing to continue performance.

Further, a cost-reimbursement contractor is expected to project its indirect cost rate and to inform the contracting officer if the projected indirect costs are expected to cause an overrun, even though final overhead rates are not established until after the contract is completed. Notice that the indirect cost rate is expected to increase does not constitute notice that the new rates will cause an overrun unless specifically stated and accompanied by a revised estimated cost of the contract.

Contractors are invited to contact their respective contracting officers if they have any further questions.

NOTICE

DIRECTORY OF INTERNATIONAL OPPORTUNITIES IN BIOMEDICAL AND
BEHAVIORAL SCIENCES

P.T. 22; K.W. 1200170, 0404000

FOGARTY INTERNATIONAL CENTER

The Fogarty International Center (FIC) of the National Institutes of Health, (NIH) announces the availability of a limited number of booklets entitled Directory of International Opportunities in Biomedical and Behavioral Sciences. This publication is available to individuals who are seeking information about fellowship support in biomedical and behavioral sciences.

To receive a copy of this booklet, please send a self-addressed label with your request to the following address:

International Research and Awards Branch
Building 38A - Room 613
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

NOTICE

PROGRAM PROJECT RESEARCH GRANT APPLICATION

SPECIAL INSTRUCTIONS FOR PHS FORM 398

P.T. 34; K.W. 0404002, 0503016, 1200180

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) announces the availability of special instructions to assist applicants in preparing program project applications using PHS Form 398. These instructions should be used to submit program project (P01) proposals which are likely to be assigned to NIA for support and are to be used in conjunction with the Program Project Research Grant Special Directives previously published in the NIH Guide for Grants and Contracts, Vol. 12, No. 4, April 22, 1983.

Copies of the above materials may be obtained by request at the address below:

Scientific Review Office
National Institute on Aging
Office of Planning and Extramural Affairs
National Institutes of Health
Building 31 - Room 5C-12
Bethesda, Maryland 20205

Telephone: (301) 496-9666

NOTICE

AVAILABILITY OF FROZEN SERUM PANELS

P.T. 36; K.W. 1200090, 1200140, 1200370

NATIONAL CANCER INSTITUTE

A variety of serum components (e.g., peptide hormones, viral antigens, isoenzymes, glycoproteins, antibodies, immune complexes, tumor-associated antigens, carbohydrates, phospholipids, nucleosides, etc.) have been reported to be useful in cancer diagnosis and/or in monitoring cancer treatment or recurrence. The National Cancer Institute (NCI) is interested in evaluating serum assays that are potentially useful in the diagnosis of cancer. Coded panels composed of 1 ml aliquots of pretreatment frozen sera from patients with various neoplasms, from benign disease patients, and from healthy controls are available to investigators to evaluate assays in which preliminary results indicate the ability to discriminate between cancer patients and controls. Promising results may form the basis for a subsequent grant application. Preliminary data documenting a useful test must be submitted and should include: a brief description of the assay, results in patients with cancer, results in patients with non-malignant disease, results in healthy control subjects and reprints of published work, if available. Request for a coded serum panel should be sent to:

Diagnosis Serum Panels
Project Officer NCI-Serum Bank
Diagnosis Branch
Westwood Building - Room 10A10
5333 Westbard Avenue
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA84-ES-03RAT PANCREATIC EXOCRINE LESIONS: BIOLOGICAL NATURE AND POSSIBLE
ROLE OF VEGETABLE OIL IN FORMATION OF THESE LESIONS IN GAVAGE STUDIES

P.T. 34; K.W. 1007009, 1002014, 0202022, 1200790

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Application Receipt Date: July 25, 1984

The Toxicology Research and Testing Program (TRTP) of the National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS) invites cooperative agreement applications to aid in defining the relationship of dietary oil and increased incidence of pancreatic acinar cell proliferative lesions found in rats. A means to provide an accepted classification scheme of rat proliferative exocrine pancreatic lesion based on the biological nature of the lesions is also considered important. This Request for Applications (RFA) will be utilized to assist and stimulate research in an area of importance to toxicologists evaluating oil gavage studies, nutritionists concerned about the levels of dietary oil, oncologists working in the area of pancreatic carcinogenesis and finally physiologists studying the role of pancreatic trophic hormone interactions with dietary oil.

An applicant, if funded under this RFA will be supported through the cooperative agreement mechanism in accordance with the policies of the Public Health Service (PHS) and the National Institutes of Health (NIH).

An applicant may apply for a project period of up to five years under the RFA. The number of awards, up to three, will be dependent upon the merit of the respondents. The specific amount to be funded will depend upon the merit of the applications received and the availability of funds. It is the intent of this RFA to create or fund a program(s) of research in a location(s) where a critical mass of resources and qualified investigators already exists or can be assembled by the time of the award.

The awardee will have the primary responsibility for the planning and direction of the proposed research. This will involve active participation and interaction with the NTP/NIEHS staff on both administrative and scientific matters. NTP/NIEHS staff will periodically review progress to insure conformation to the award.

The receipt date for application is July 25, 1984. Prospective applicants should obtain a copy of the RFA before applying. The RFA and additional information are available from:

Gary A. Boorman, D.V.M., Ph.D.
Head, Tumor Pathology, CPB, TRTP
National Institute of Environmental
Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-12

DIETARY MARKERS FOR EPIDEMIOLOGIC STUDIES OF CANCER

P.T. 34; K.W. 1002014, 0701013, 0202022, 1003002, 1200780

NATIONAL CANCER INSTITUTE

Application Receipt Date: September 15, 1984

I. BACKGROUND

The current emphasis on nutritional factors as modulators of carcinogenesis in human populations has created an increased awareness of the need for biologic markers of present and past dietary exposures that might alter cancer risk. Experimental animal studies have indicated that the intake of specific dietary components is an important determinant of cancer risk. Attempts to apply these findings to the human situation are hindered by the difficulty of classifying individuals into intake (or exposure) categories.

In terms of nutritional status, attempts at assessment are usually based on questionnaire or interview-derived information. Problems exist in determining the extent to which such data reflect actual intake (e.g., selective recall, limited knowledge of food composition and complexity of diet), the extent to which utilization is a measure of bioavailability (e.g., absorption efficiency and the possibility that specific dietary components may be ingested in a form which renders absorption difficult or impossible) and individual variability in metabolic handling of substances after absorption.

It would clearly be advantageous to have available biochemical measures (preferably minimally invasive) which would provide unambiguous markers of the level and distribution of dietary constituents in individuals. Such methodology would facilitate the design, conduct and interpretation of epidemiologic studies focused on the relationship between diet, nutrition and cancer risk.

Because of the latency period involved in the carcinogenic process, it can be anticipated that cancer risk will have been modulated by dietary patterns which existed at some time in the past as well as those in the present. These past events are not always well defined by data on current dietary patterns for several reasons; among these, the fact that dietary patterns may vary significantly over time and because of our limited knowledge of the changing composition of foods. Markers of both present and past dietary experience are, therefore, of special interest in cancer epidemiology and some evidence from experimental studies suggests a potential for the development of markers for validation of present exposure or which reflect integrated past exposure.

Examples of markers which might provide measures of present exposure levels would include urinary 3-methylhistidine occurring in skeletal muscle as an estimate of muscle meat consumption and detection of 2,3-dihydro-2-(7'-guanyl)-3-hydroxy-aflatoxin-B1 as an indicator of exposure to aflatoxin-B1 in the diet. Examples of past exposure would include the existence of persistent DNA or protein adducts following exposure to specific materials, the accumulation of substances in the body which are excreted extremely slowly, and alterations in tissue composition which reflect past intake.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to encourage investigations designed to identify, characterize and validate markers of present or past dietary exposure which could be useful in the validation or the conduct of nutritionally focused studies in cancer epidemiology. Clearly, the more relevant to cancer risk and the more persistent the marker the greater its utility for this purpose. Because the methods to be developed will ultimately be utilized in epidemiological studies, it is important that consideration be given at the outset to feasibility in this context. Such factors as ease of conduct and expense as well as collection, storage and transport problems should be considered along with the accuracy and validity of the method. It is not our intent to exclude animal studies in this context where they are necessary for the development and validation of methodologies which will ultimately be applied to the human situation. The range of materials, for which markers of exposure are of interest, is extremely diverse. Included would be any foods and beverages, food groups or components, nutrients or trace elements derived from dietary sources which have been proposed to alter the risk of malignancy and for which human exposure is likely to have occurred. Documentation of inter-individual variation, both in absorption and metabolic utilization and in persistence of markers, is of interest.

III. INQUIRIES

For further information and a copy of the RFA, contact:

Dr. A. R. Patel
Extramural Programs Branch
Epidemiology and Biostatistics Program
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 8C-16
Bethesda, Maryland 20205

Telephone: (301) 496-9600 (9601 or 9602 or 9603)

ANNOUNCEMENT

NCI COOPERATIVE MINORITY BIOMEDICAL PROGRAM

P.T. 34; K.W. 1002014, 1014002, 1200180, 1200950

NATIONAL CANCER INSTITUTE

I. DESCRIPTION

The National Cancer Institute (NCI) provides support for minority researchers through the Cooperative Minority Biomedical Program (CMBP).

Domestic research institutions already receiving NCI grants and interested in including minority researchers in their cancer research may submit a supplemental grant application for this purpose. Approved applications will be funded as supplements to previously peer reviewed active grants. These may include, but are not limited to, individual project (R01) and program project (P01) grants.

II. OBJECTIVES

The CMBP provides support to minority scientists to assist in providing increased opportunities for enlarging their capabilities in cancer research and to influence more minority scientists to develop careers as cancer investigators.

III. PROJECT EVALUATION

The NCI Program Director in conjunction with the Cancer Minority Program Advisory Committee (CMPAC) will determine the appropriateness of the supplement to the grant using the following criteria: the proposed research described in the supplemental application must fit within the scope of the approved and funded project; the curriculum vitae of the minority scientist must indicate that he/she could be expected to achieve the objectives of this project; and the length of time requested must be reasonable for achieving the objective. Initial merit review will be managed by the Division of Extramural Activities (DEA), NCI, following which a recommendation will be made by the National Cancer Advisory Board (NCAB).

IV. ELIGIBILITY

Any domestic institution with an active cancer research grant is eligible to submit a supplemental application on behalf of a principal investigator for the exclusive purpose of including minority researchers in the project.

- A. Minority Investigator - A minority investigator may be described as a U.S. citizen from an under-represented ethnic American nationality (e.g., Black, Hispanic, Native American, Asian or Pacific Islander). The minority investigator is expected to provide a complete curriculum vitae which includes a list of any research publications. The minority investigator(s) may be affiliated with the applicant institution(s) or some other institution. The program is not intended to pay stipends for student

trainees or support candidates without any research background. The investigator must be willing to devote a minimum of 30 percent of his/her time to the research project.

- B. Research Project - The proposed project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort in an already approved objective of the research project or propose to enhance the effectiveness of the overall research. The nature of the research should provide the minority investigator an opportunity to contribute intellectually to the program and to broaden his/her own potential. The scope of the project will generally be comprehensive enough to require at least two years for completion and the supplemental application should include such a research plan and projected budget sheets. With appropriate justification a one-year application may be acceptable. No new supplemental applications will be accepted in the final year of the current award.

V. FUNDING

Funding will be made in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis. Continuing support for the second (or subsequent) year will depend upon approval of a satisfactory annual progress report and proposed budget from the minority investigator submitted with the principal investigator's non-competing continuation application. Funding for the supplement is always contingent on funding of the parent grant. Each minority investigator budget shall not exceed \$25,000 in direct costs and may not include equipment. Supplemental awards made under this program are for the sole purpose of facilitating participation by minority investigators as described above.

VI. HOW TO APPLY

The principal investigator should submit a supplemental grant application through the institution on the Standard Form PHS 398, limited to the following: (1) Face page, at the top of which the applicant must designate the grant number of the active grant and specifically state "Minority Investigator Supplement" (For example, grant number CA-12345-02 "Minority Investigator Supplement"); (2) budget page (excluding equipment); (3) biographical sketch of the minority researcher; and (4) outline of the research project as it relates to the parent grant.

Applications received fewer than 90 days prior to a scheduled NCAB meeting may be reviewed at the subsequent NCAB meeting.

The original and four (4) copies of the application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please send two (2) copies to:

Mr. Hernon H. Fox
Referral Office
National Cancer Institute
National Institutes of Health
Westwood Building - Room 826
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENTBIOCHEMISTRY AND PHARMACOLOGY PROGRAM

P.T. 34; K.W. 1200250, 1003012, 1201200

NATIONAL CANCER INSTITUTE

The Biochemistry and Pharmacology Program of the Division of Cancer Treatment, National Cancer Institute (NCI), announces the following guidelines to assist investigators preparing grant applications in the synthetic chemistry area including synthesis of natural products. These criteria set forth the objectives of the preclinical drug development program of the NCI. The Institute will express interest in grant applications which include at least one of the following:

- o A rationale based on biochemical, pharmacological or experimental therapeutic considerations that the target molecules are likely to be potential anticancer agents.
- o Positive antitumor data in specific test systems with members of proposed structural entities or their analogs.
- o Compounds needed for follow-up studies and which are not available in adequate quantity from commercial or natural sources.
- o A confirmation from the NCI or from other institutions or laboratories indicating need and interest for synthesis of proposed compounds.

For more information, call or write:

M.V. Nadkarni, Ph.D.
Program Director for Grants
Biochemistry and Pharmacology Program
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Blair Building - Room 401
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8706

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HD-04

CHILD CARE, FERTILITY, AND FEMALE LABOR FORCE PARTICIPATION

P.T. 34; K.W. 0404000, 0413000, 0413002, 0404004

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: August 15, 1984

I. SCIENTIFIC PROGRAM OBJECTIVES

The Demographic and Behavioral Sciences Branch (DBSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), supports research on the antecedents and consequences of fertility and fertility regulation. The RFA, for which this is a notice of availability, invites scientists to submit grant applications for the support of research on the interrelations among child care arrangements for employed parents, fertility, and female labor force participation. The DBSB has supported the collection of data on the care of preschool-age children, specifically in the June 1977 and June 1982 Current Population Surveys of the Census Bureau and the National Longitudinal Survey--Youth Cohort of the Department of Labor, Rounds Four, Five and Six. Investigators are encouraged to use these public data sets in research on the use of child care arrangements by parents, especially in relation to fertility, female labor force participation, and other population issues. However, it should be emphasized that research need not be limited to these data sets or to preschool-age children. Researchers may use extant data, new data, or a combination of both. The research may be multidisciplinary or may be conducted within a single discipline. In addition to utilizing United States data, investigators may use comparative, crosscultural, transnational, or historical approaches. However, this Request for Applications is focused on a fairly narrow range of research issues, specifically the interrelationship of child care, fertility and female labor force participation.

II. MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA).

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Copies of the complete RFA may be obtained from:

Wendy Baldwin, Ph.D.
Demographic and Behavioral Sciences Branch
National Institute of Child Health
and Human Development
Landow Building - Room 7C25
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

AVAILABILITY OF ALCOHOL RESEARCH GRANTS

P.T. 34; K.W. 0404000, 0404003, 0414000, 0415000, 0701013, 0701038, 0701042, 1002019, 1002030, 1200420, 1201000, 1201270

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

I. INTRODUCTION AND PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) makes grant awards for basic and applied alcohol research projects. Grant support is available to develop knowledge in a wide range of areas relevant to alcohol-related problems and alcoholism: studies of the physiologic and behavioral mechanisms leading to pathologic drinking behavior; studies of alcohol-induced organ damage; and studies of clinical, behavioral and environmental factors that will lead to more effective diagnosis, prevention, and treatment techniques. Applications are especially encouraged for projects focused on the development and validation of new and improved treatment approaches, the reduction of alcohol-related deaths and trauma, as well as the prevention of alcoholism and alcohol-related problems.

II. AREAS OF INTEREST

The Institute supports alcohol-relevant research involving all the life-science disciplines including: chemistry, biochemistry, physiology, toxicology, pharmacology, neurosciences, genetics, molecular biology, psychology, sociology, anthropology, psychiatry, epidemiology and other related medical fields. Some areas of interest are:

Biomedical and Genetic research, such as the study of alcohol metabolism including research which utilizes molecular biological methodology, genetic variability to the metabolic, physiologic and neurologic effects of alcohol, identification of biological and environmental factors which contribute to the risk for alcoholism and alcohol-derived disease including the development of animal models;

Epidemiologic research, such as studies of drinking patterns and derived health consequences among differing demographic groups; study of residual risk for organ pathology among former alcoholics, and how factors such as duration of abstinence impact on this risk;

Neuropharmacological research, such as the cellular and molecular basis of alcohol intoxication, the role of the nervous system in tolerance and dependence including genetic factors contributing to expression of these phenomena, the effects of alcohol on neurotransmitters, neuroendocrine systems, membrane structure and function, and the study of alcohol and drug interactions;

Pathology-related research on the nature of alcohol-associated diseases, the relationship between alcoholism and other behaviorally induced disorders, the teratogenic effect of alcohol on pregnancy outcome, and differential susceptibility to the effects of alcohol based upon genetics, gender or other population characteristics. Particularly encouraged are studies on the role of alcohol in death and injury arising from vehicular, work-related, recreational and home accidents, and the medical management of trauma in intoxicated patients;

Prevention research, such as the study of preventive interventions to reduce the incidence of alcohol-related disorders and alcoholism, and to promote risk-reducing behaviors; the development of methods for the detection of high-risk precursors; and the influence of law and policy on the incidence and prevalence of alcohol problems;

Psychosocial research, such as the cognitive effects of alcohol abuse, the social and cultural differences in alcohol consumption, and the role of drinking in relation to accidents, violence, and crime;

Treatment research, such as the assessment of treatment outcome, the study of treatment efficacy, and the identification of factors that may affect the willingness of individuals to enter into treatment programs including the study of early identification and intervention in the workplace. Of special concern are studies that match characteristics of patients/clients (e.g., age, gender, personality traits, ethnicity) with specific treatment modalities.

In all of the above areas, NIAAA is particularly interested in projects which focus on alcohol-related problems of women, adolescents and youth, the elderly and minority ethnic groups.

III. APPLICATION PROCEDURES AND ELIGIBILITY

Further information on specific research areas supported by NIAAA and the processes for submission, review, and award of grant applications may be obtained by requesting a copy of the Alcohol Research Grants program from the National Clearinghouse for Alcohol Information, Box 2345, Rockville, Maryland 20852.

Although not mandatory, applicants desiring support under this announcement are encouraged to consult with program staff of NIAAA prior to official submission of an application. Inquiries should be made to:

Dr. Helen Chao
 Chief, Biomedical Research Branch
 or
 Dr. Ernestine Vanderveen
 Chief, Clinical and Psychosocial Research Branch
 Parklawn Building - Room 14C-17
 5600 Fishers Lane
 Rockville, Maryland 20857

Telephone: (301) 443-4223

Applications received in response to the announcement will be assigned for review and funding consideration in accordance with established Public Health Service (PHS) policies and procedures. Grant awards are made under the Authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241).

Applications received in response to the announcement will be assigned for review and funding consideration in accordance with established Public Health Services (PHS) policies and procedures. Submission of an application for a NIRA precludes concurrent application for a Research Scientist Development or Research Scientist Award, a National Research Service Award, or any similar award from ADAMHA or NIH. Individuals already receiving support from a NIRA are also precluded from applying for concurrent support under the above listed programs.

An applicant for a New Investigator Research Award may apply separately for a research project grant for a different project if there is no conflict with the time or other commitments to the NIRA. Awards will be made under the authority of Sections 301 and 510 of the Public Health Service Act.

ANNOUNCEMENT

AVAILABILITY OF NEW INVESTIGATOR RESEARCH AWARDS

P.T. 34; K.W. 0404000, 0404003, 0414000, 0415000, 0701013, 0701038, 0701042, 10020119, 1002030, 1200420, 1201000, 1201270

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

I. INTRODUCTION AND PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) encourages basic and applied research on all biomedical and psychosocial aspects of alcoholism and alcohol-related health problems. This announcement solicits applications for New Investigator Research Awards (NIRAs). The NIRA program is designed to help new investigators develop their research interests and capabilities in alcohol-related biomedical and psychosocial research. Support of these projects is expected to aid researchers bridge the transition from training status to independent investigator. In addition, this program seeks to attract established scientists who have not been principal investigators on NIAAA supported projects. NIAAA is interested in applications from all well qualified individuals. Women and minority candidates, in particular, are encouraged to apply.

II. AREAS OF INTEREST

NIAAA invites applications for research grants on biomedical, behavioral, clinical, sociocultural and epidemiological factors associated with the use or abuse of alcohol, the prevention and treatment of alcohol-related health problems, and the consequences of these health problems. Some areas of interest are:

Biomedical and Genetic research, such as the study of alcohol metabolism including research which utilizes molecular biological methodology, genetic variability to the metabolic, physiologic and neurologic effects of alcohol, identification of biological and environmental factors which contribute to the risk for alcoholism and alcohol-derived disease including the development of animal models;

Epidemiologic research, such as studies of drinking patterns and derived health consequences among differing demographic groups; study of residual risk for organ pathology among former alcoholics, and how factors such as duration of abstinence impact on this risk;

Neuropharmacological research, such as the cellular and molecular basis of alcohol intoxication, the role of the nervous system in tolerance and dependence including genetic factors contributing to expression of these phenomena, the effects of alcohol on neurotransmitters, neuroendocrine systems, membrane structure and function, and the study of alcohol and drug interactions;

Pathology-related research, on the nature of alcohol-associated diseases, the relationship between alcoholism and other behaviorally induced disorders, the teratogenic effect of alcohol on pregnancy outcome, and differential susceptibility

to the effects of alcohol based upon genetics, gender or other population characteristics. Particularly encouraged are studies on the role of alcohol in death and injury arising from vehicular, work-related, recreational and home accidents, and the medical management of trauma in intoxicated patients;

Prevention research, such as the study of preventive interventions to reduce the incidence of alcohol-related disorders and alcoholism, and to promote risk-reducing behaviors; the development of methods for the detection of high-risk precursors; and the influence of law and policy on the incidence and prevalence of alcohol problems;

Psychosocial research, such as the cognitive effects of alcohol abuse, the social and cultural differences in alcohol consumption, and the role of drinking in relation to accidents, violence, and crime;

Treatment research, such as the assessment of treatment outcome, the study of treatment efficacy, and the identification of factors that may affect the willingness of individuals to enter into treatment programs including the study of early identification and intervention in the workplace. Of special concern are studies that match characteristics of patients/clients (e.g., age, gender, personality traits, ethnicity) with specific treatment modalities.

In each of the above areas, NIAAA is particularly interested in projects which focus on alcohol-related problems of women, adolescents and youth, the elderly and minority ethnic groups.

III. APPLICATION PROCEDURES AND ELIGIBILITY

A NIRA award is restricted to an individual who has not been a principal investigator on a NIAAA research project. An investigator with previous support under either a fellowship or training grant, however, is eligible. The principal investigator must have completed his or her formal professional training. New investigators shall have no more than five years of research experience, after completion of training, when the award is made. Those applicants wishing to re-focus their careers to alcohol research need meet only the criterion of no previous NIAAA support.

A copy of the full NIRA program announcement may be obtained by writing to the National Clearinghouse for Alcohol Information, P.O. Box 2345, Rockville, Maryland 20852. Further information on program requirements and application procedures can also be obtained from:

Dr. Helen Chao
Chief, Biomedical Research Branch

or

Dr. Ernestine Vanderveen
Chief, Clinical and Psychosocial Research Branch
Parklawn Building - Room 14C-17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4223

ANNOUNCEMENT

ISRAELI MINISTRY OF HEALTH POSTDOCTORAL RESEARCH FELLOWSHIPS

P.T. 22, 48; K.W. 1200170, 1200180, 0404000, 0112066

FOGARTY INTERNATIONAL CENTER

Application Receipt Date: October 1, 1984

I. BACKGROUND

The Israeli Ministry of Health (IMOH) provides postdoctoral fellowships to U.S. health scientists to conduct biomedical research in Israel. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical and behavioral sciences with emphasis on heart diseases, aging, cancer, and human reproduction and child development. These fellowships support scientists who are at various stages of their research careers -- from those in the formative stages to the more established scientists. The program does not provide support for activities that have as their principal purpose brief observational visits, attendance at scientific meetings, or independent study.

The program is administered for the IMOH by the Fogarty International Center (FIC), National Institutes of Health (NIH).

II. ELIGIBILITY

Applicants for the program must meet the following requirements:

- o U.S. citizenship or permanent U.S. resident,
- o A doctorate in one of the clinical, biomedical, or behavioral sciences,
- o Professional experience in the proposed area of research.

III. SUPPORT

The IMOH will provide the following support:

1. STIPEND. The level of stipend is comparable to the fellow's counterpart in Israel and is determined by the experience of the applicant at the time of award. Professional experience in academic, clinical and/or institutions may be considered relevant experience for scientists who are in the formative stage of their research career. Fellows may accept sabbatical salary, concurrent royalties, or other income from past services if reported in the application.

2. TRAVEL. Round-trip, economy-class air fare expenses are provided for fellows from point of origin in the United States to the Israeli host institution. No reimbursement will be made for any other expenses en route, nor for costs of transporting personal or household effects.

3. HEALTH INSURANCE. Accident insurance coverage is provided for fellows during their stay in Israel. Each fellow is strongly urged to purchase insurance in the United States to cover the round trip transit period for himself/herself and accompanying family dependents.

IV. DURATION OF PARTICIPATION

Fellowships are awarded for a minimum of 3 months to a maximum of 12 months. The starting date of the fellowship is set by mutual agreement of the applicant and the sponsoring institution, provided it is within the twelve month period immediately following the date of the award. In exceptional cases, fellowships may be extended for an additional period of time if mutually agreed to by the Israeli sponsor and the IMOH.

V. APPLICATION AND SELECTION

Information and applications are provided by the Fogarty International Center. In addition to biodata and reference reports, the applicant will be required to include a clear and explicit description of the proposed activity to be carried out in Israel and the benefit expected from the experience. The proposed research should be in one of the four areas supported under this program, however the IMOH will consider applications in other areas of biomedical and behavioral research. It is the applicant's responsibility to agree upon a research project with a scientific sponsor in Israel either through direct correspondence or through correspondence conducted on the applicant's behalf by a senior scientist in the United States with any Israeli scientific colleague. The Israeli sponsor's portion of the application should indicate that he or she is prepared to guide and administer the proposed research project, and can provide the necessary facilities.

The receipt date for applications is October 1. Applications are reviewed for scientific merit by the NIH before being transmitted to IMOH for final selection. Candidates will be notified shortly thereafter by the IMOH of the results

VI. INQUIRIES AND APPLICATION KITS

Please direct all inquiries about this program and requests for application kits to:

Chief, International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

VISITING SCIENTISTS PROGRAM OF THE NATIONAL SCIENCE COUNCIL, TAIWAN

P.T. 22, 48; K.W. 1200170, 1200180, 0404000, 0112133

FOGARTY INTERNATIONAL CENTER

I. BACKGROUND

The Visiting Scientists Program of the National Science Council in Taipei, Taiwan (NSCT) provides a limited number of research fellowships to United States health scientists to conduct research or to lecture in Taiwan. The purpose of these fellowships is to enhance the exchange of information in the biomedical and behavioral sciences. The program does not provide support for activities that have as their principal purpose a brief observational visit, attendance at a scientific meeting, or independent study.

The NSCT is interested in receiving applications in the areas of cancer, cardiovascular diseases, stroke, infectious diseases, environmental health, blood banking, and animal models. Whereas the above listed areas are preferred, the NSCT will also accept applications in other areas of biomedical research.

The program is being announced for the NSCT by the Fogarty International Center (FIC), National Institutes of Health (NIH).

II. TYPES OF AWARDS

The NSCT Visiting Scientists Program provides opportunities for scientists at three career levels: (1) Special Chair, (2) Visiting Research Professor, and (3) Visiting Specialist. Internationally prominent scientists may apply for the Special Chair Award which encompasses research in areas that are highly relevant to Taiwan. Scientists who hold a full professorship may apply for the Visiting Research Professor Award. In this capacity they would guide advanced research projects or lecture on recent developments in the field of science. Scientists who have at least 5 years postdoctoral experience, or whose scientific specialty has not been fully developed in Taiwan, may apply for the Visiting Specialist Award.

III. SUPPORT

The NSCT will provide the following support:

1. **Living Expenses:** The living expenses for the Special Chair Award range from *NT \$56,000 to NT \$88,000 per month. For the Visiting Research Professor and the Visiting Specialist Awards, the living expenses are NT \$46,000 to NT \$76,000 per month. The level of payment for each award is determined by the NSCT and is based on the qualifications of the applicant. The living expenses are written into the contract.

The money paid for living expenses is subject to income withholding tax according to Taiwan's Income Tax Law. The tax return must be filed by the awardee, but the host institution should provide necessary assistance.

2. **Travel:** For a visit of 6 months or less, a round-trip, direct-route, economy-class air ticket will be provided to the awardee. For a visit of over 6 months but less than 10 months, two round-trip, direct-route, economy-class air tickets will be provided for use by the awardee and his/her spouse. For a visit of over 10 months, two round-trip, direct-route, economy-class air tickets will be provided for use by the awardee and his/her spouse, and up to two single trip, direct-route, economy-class air tickets may be provided for use by the awardee's children who are 18 years of age or younger. The awardee is advised to take China Airlines in his/her travel to and from Taiwan, if possible.
3. **Housing:** If the host institution provides a house for the awardee, there is no housing allowance. If housing is not provided, there is a housing allowance of NT\$4,000/month for an awardee unaccompanied by family and NT\$8,000/month for an awardee accompanied by family.
4. **Medical Insurance:** If the awardee's U.S. insurance policy does not give adequate protection for the insured while outside the United States, the awardee may purchase medical and casualty insurance from the Central Trust, Taipei. In such case, the awardee will be required to pay 35% of the premium and the NCST will contribute the remainder.

IV. DURATION OF AWARD

The duration of the award is determined by the work plan but should not be less than three months. The contract term does not exceed 1 year, but the contract may be renewed if necessary.

V. APPLICATION AND SELECTION

To be considered for an award, the candidate must apply to the NSCT at least 3 months in advance of the intended commencement date of the visit. The request should be accompanied by a workplan with the following content:

1. Title of the work
2. Brief statement about the nature of the work
3. Detailed description of the plan with a time schedule
4. Expected achievements and their contributions to science development in Taiwan
5. Curriculum vitae and publication list of the applicant
6. Relevance of the workplan to the overall institutional program

7. A letter of invitation from the host that includes information about the manpower available from the host institution to support the workplan, and availability of space, library facilities, instruments, etc. for the proposed work.

Applications should be sent to:

Dr. Ti-Sheng Lu
Division of International Programs
National Science Council
2 Canton Street
Taipei, Taiwan

VI. TERMINATION OF AWARD

The host institution will submit to the NSCT a final report in triplicate within 2 months after the termination of the award. The report should include all accomplishments resulting from the award.

VII. INQUIRIES ABOUT AND REQUESTS FOR APPLICATIONS SHOULD BE SENT TO:

Chief, International Research
and Awards Branch
Fogarty International Center
National Institutes of Health
Building 38A - Room 613
Bethesda, Maryland 20205

Public Health Service

GRANTS POLICY STATEMENT



ADDENDUM

INTRODUCTION

Since the issuance of the revised Public Health Service (PHS) Grants Policy Statement, dated December 1, 1982 (DHHS Publication No. 82-50,000), we have found there is a need to modify certain portions of the document. This addendum reflects additions to, corrections or clarifications of, or deletions from, that PHS Grants Policy Statement.

The addendum becomes part of the existing PHS Grants Policy Statement and should be maintained with it. In general, the addendum will be effective for grants with budget periods beginning on or after April 1, 1984. However, two exceptions are noted:

1. The expanded Institutional Prior Approval System described in this document will be effective on April 1, 1984, for grants active on that date—without regard to budget period beginning dates.
2. Where a policy in the addendum previously was issued in the PHS Grants Administration Manual (GAM), the effective date of the GAM material shall take precedence.

Questions concerning the contents or preparation of this addendum or the PHS Grants Policy Statement should be directed to the Grants Management Branch, Division of Grants and Contracts, ORM/OM/PHS, 5600 Fishers Lane, Rockville, MD 20857.

Wilford J. Forbush
Deputy Assistant Secretary
for Health Operations and
Director, Office of Management

ADDENDUM TO PUBLIC HEALTH SERVICE GRANTS POLICY STATEMENT

Page i—*Preface*—Under the OASH description, the last sentence should be expanded to read as follows: "Grant and cooperative agreement programs are administered in OASH by the National Center for Health Services Research, the Office of Disease Prevention and Health Promotion, and the Office of Population Affairs."

Page 1—*Effective Date*—The PHS Grants Policy Statement is effective for all awards with budget period beginning dates on or after December 1, 1982.

Page 2—*Approved Budget*—The following sentence, which was omitted from the current definition, should be reinserted at the end: "Any expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grant in the same proportion as the percentage of Federal/non-Federal participation in the overall budget."

Page 2—*Glossary: Competitive Segment*—The word "competitive" was misspelled.

Page 3—*Glossary: Federal Institution*—"Federal hospitals, such as VA hospitals" are not to be excluded from the definition of a Federal institution. Thus, the second sentence should be shortened to read as follows: "Howard and Gallaudet Universities are not considered as Federal institutions under this definition."

Page 6—*New Applications*—This paragraph references the external review requirements of OMB Circular A-95, as do a number of topics under the major heading "PREAWARD PROCESS" (pages 9-20). Within that major heading, the principal material on the Circular is set forth on pages 17-19 (under the title "EXTERNAL REVIEW REQUIREMENTS"). All of that material, *except* for the section on "Health Planning and Development Reviews," should be deleted (three sections) and the following section should be substituted (on page 17):

"Executive Order 12372

Effective September 30, 1983, Executive Order 12372 (Intergovernmental Review of Federal Programs) directed OMB to *abolish OMB Circular A-95* and establish a new process for consulting with State and local elected officials on proposed Federal

financial assistance. The Department of Health and Human Services has implemented the Executive Order through regulations at 45 CFR Part 100 (Intergovernmental Review of Department of Health and Human Services Programs and Activities). The objectives of the new approach are to (1) increase State flexibility to design a consultation process and select the programs it wishes to review, (2) increase the ability of State and local elected officials to influence Federal decisions, and (3) compel Federal officials to be more responsive to State concerns, or explain the reasons.

The regulations at 45 CFR Part 100 were published in the *Federal Register* on June 24, 1983, along with a notice identifying the Department's programs that are subject to the provisions of Executive Order 12372. Applicants should contact the Governor's office for information regarding the particular consultation (review) process designed by their State."

Page 7—*A Noncompeting Extension*—In the first paragraph, reference to administrative approval by the "Grants Management Officer or the PHS awarding office" should read "of" the PHS awarding office.

Page 11—*Paragraph G*—The words "section 501 of the Mental Health Systems Act (Public Law 96-398)" should be deleted.

Page 13—*Human Subjects*—In the first sentence, the reference to "P.L. 93-348" should be deleted.

Page 16—*Information Collection*—The reference to OMB Circular A-40 should be deleted, because the circular has been abolished. The current report clearance procedures are set forth in OMB regulations at 5 CFR Part 1320, "Controlling Paperwork Burdens on the Public."

Page 19—*Application Receipt*—The Department of Health and Human Services has approved a deviation from the postmark date requirement for grant applications processed through NIH's Division of Research Grants (DRG). The DRG system requires that applications must be *received* by the published application receipt dates. A package carrying a legible proof-of-mailing date assigned by the carrier, and which is no later than one week prior to the receipt date, is also acceptable. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be

extended to the following work day. The receipt date will be waived only in extenuating circumstances. To request such a waiver, include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of the application.

Page 22—*Individual Fellowships*—The maximum activation period for individual fellowships under the National Research Service Award program is 6 months from the time of award.

Page 23—*Terms of Award*—This section states that grant terms may be changed with the consent of the Grants Management Officer. It should be understood that such changes are permitted only when consistent with applicable statutes and regulations and deemed to be in the best interest of the Government.

Page 24—*Cost Sharing*—In the first paragraph, “research grants to Federal institutions” are cited as an example of allowing “less than full recovery of indirect costs to satisfy the requirement for cost sharing.” Current policy (1) prohibits grant funds from being used to pay indirect costs incurred by Federal institutions, and (2) relieves such grantees from a cost sharing requirement.

Page 25—*General Requirements for Matching and Cost Sharing*—The last sentence in the first column (extending to the second column) should be revised to read as follows:

“Where a fixed minimum percentage of match is not specified by legislation or regulation and the actual reported level of match does not meet the previously negotiated percentage (as shown on the notice of grant award), the PHS awarding office may either reduce the Federal grant, or, where circumstances warrant, make a retroactive adjustment and accept a lower percentage of match.”

Page 28—*Alteration and Renovation*—In the second column, item 9.c. states that the amount of project funds rebudgeted for alteration and renovation during a budget period cannot exceed \$1,000 without prior approval. However, in accordance with page 45 (as revised by this addendum), grantee organizations subject to an Institutional Prior Approval System are to use that system for alteration and renovation expenditures not to exceed \$5,000.

Page 32—*Equipment Purchase*—The requirement that “PHS awarding office prior approval” be obtained for the purchase of special-purpose equipment costing \$1,000 or more per unit is part of a general statement on the subject of equipment purchases and associated prior approvals. All

required prior approvals must be given by the PHS awarding office, unless such approval authority has been delegated to the grantee by means of an Institutional Prior Approval System (see pages 44-45). In the case of special-purpose equipment costing \$1,000 or more, the method for obtaining prior approval has been delegated to certain grantee institutions (e.g. colleges, universities, hospitals, research institutes, and research foundations) for treatment under an Institutional Prior Approval System.

Page 32—*Equipment Purchase*—The second sentence states (in part) that “PHS awarding office prior approval is required for the purchase of general-purpose equipment costing \$500 or more per unit.” However, in accordance with page 45 (as revised by this addendum), grantee organizations subject to an Institutional Prior Approval System are to use that system for general-purpose equipment not to exceed \$1,000 per unit.

Page 33—*Insurance (Equipment)*—The paragraph on Government-owned equipment is changed to read as follows: “Costs of insurance on Federal Government-owned equipment are allowable with prior approval.”

Page 34—*Meals*—In the last sentence the word customer should be “consumer.”

Page 34—*New Release Costs*—The paragraph on this subject is changed to read as follows: “Allowable with prior approval. However, the requirement for prior approval does not apply to educational institutions.”

Page 35—*Rental or Lease of Facilities and Equipment*—The following paragraph should be substituted for the next to last paragraph on the page:

“When an institution transfers property to a third party through sale, lease or otherwise, and then leases the property back from that third party, the lease cost that may be charged to PHS projects generally may not exceed the equivalent of the cost of ownership.”

Pages 36-37—*Salaries and Wages*—The following paragraph, which was omitted from this section, should be reinserted:

“*Research [career] development*: Grant funds budgeted for an individual’s salary but released as the result of transfer of support of an individual to a PHS research or academic career program grant may not be used for any other purpose without prior approval from PHS.”

Page 38—*Trainee Costs*—The heading of the second

indented paragraph is modified to read "Institutional Allowances (Fellowships) and Training Related Expenses (Training Grants)." Further, the last two sentences in this paragraph are revised to eliminate the requirement for applicants to itemize training related expenses in training grant applications under the National Research Service Award program. The revised sentences are as follows:

"For training grants awarded under the National Research Service Award authority, training related expenses are also based on certain allowable ceiling (maximum) amounts per year for each full-time pre- and postdoctoral trainee. The relevant grant application instructions should be consulted for the current allowable ceiling amounts."

Page 38—*Stipends*—The current stipend levels are as follows:

1. Predoctoral
\$5,292 regardless of the year of award.
 2. Postdoctoral
Years of Relevant Experience
- | | |
|-----------|----------|
| 0 | \$14,040 |
| 1 | 14,736 |
| 2 | 15,468 |
| 3 | 16,236 |
| 4 | 17,040 |
| 5 | 17,892 |
| 6 | 18,780 |
| 7 or more | 19,716 |

Page 39—*Stipends*—The sentence beginning on line 10 in the second complete paragraph (first column) is incomplete. It should be deleted and replaced by the last paragraph in the section.

Page 40—*Travel*—In the first complete sentence, delete the words "under the IPAS" and add the following sentence to the paragraph (which begins on page 39): "Prior approval for domestic travel and for each foreign trip is to be obtained through the recipient's Institutional Prior Approval System."

Page 40—*Travel*—The first complete paragraph should be revised, for clarification, as follows: "For recipients that are nonprofit institutions, *other than research institutes and research foundations*, direct charges for foreign travel costs are allowable only when the travel has received awarding office prior approval."

Page 40—*Indirect Costs*—In the third line of item 3, the word following "rates" should be "of."

Page 43—*Postaward Administration*—The last sentence of the introductory paragraph should be deleted, since it is not entirely accurate in its general

references to the scope of the HHS grant appeals procedure. Readers are directed to page 57 (as revised by this addendum) for specific policy guidance on both the PHS and HHS grant appeals procedures.

Page 43—*Changes in Expenditures/Activities*—Footnote 19 should be deleted, since the prior approval requirements in item 2 (top of second column) apply to all research grants—regardless of the type of grantee.

Page 43—*Changes in Expenditures/Activities*—The second column contains a list of postaward *budgetary* changes for which prior approval must be obtained from the Grants Management Officer of the PHS awarding office. This list is not all-inclusive. As indicated within item 2, a grantee should consult the appropriate set of cost principles (see page 27) in order to compile a complete list of such "prior approval" items.

Page 43—*Changes in Expenditures/Activities*—In the second column, item 6 indicates that the procurement of general support services is subject to prior approval by the Grants Management Officer of the PHS awarding office. However, in accordance with page 45 (as revised by this addendum), grantee organizations subject to an Institutional Prior Approval System are to use that system for such procurements.

Page 45—*Institutional Prior Approval System*—The last paragraph of this section, which begins on page 44 and ends at the top of page 45, is revised to read as follows: "A grantee's Institutional Prior Approval System, which must be set forth in writing, is subject to PHS review and audit—including the individual actions taken under the system. Where a grantee institution is found to be in noncompliance with the above standards, PHS may withdraw that institution's authority to approve certain costs for PHS grants under its Institutional Prior Approval System."

Page 45—**PRIOR APPROVAL AUTHORITIES—THIS ITEM, WHICH DESCRIBES AN EXPANDED INSTITUTIONAL PRIOR APPROVAL SYSTEM (IPAS), REPRESENTS THE MOST SWEEPING MODIFICATION SET FORTH IN THE ADDENDUM.**

- Delete the two sections that separately deal with an IPAS for *State or Local Government Agencies or Indian Tribal Governments* and an IPAS for *Colleges, Universities, Hospitals, Research Institutes, and Research Foundations*.
- Substitute the following two new sections.

“For-Profit Organizations

For-profit organizations must obtain prior approval from the Grants Management Officer of the PHS awarding office for all proposed programmatic changes and rebudgeting actions for which prior approval is required.”

“All Other Grantees

This section is effective on April 1, 1984, and covers the following types of grantees: State or local government agencies, Indian tribal governments, Federal institutions, colleges, universities, hospitals, research institutes, and research foundations. These types of grantees are required to establish and use an Institutional Prior Approval System for obtaining prior approval for the following kinds of postaward budgetary changes under nonconstruction discretionary grants, where such prior approval is required by the relevant cost principles (see page 27) or by PHS policy.

1. Purchase of each individual item of special-purpose equipment having an acquisition cost of \$1,000 or more, whether as a result of rebudgeting from another budgetary category or using funds awarded for the acquisition of equipment for items not described in the approved application.
2. Patient care costs in excess of the amount in the approved budget, provided the need for patient care in the project was specifically approved by the PHS awarding office.
3. Domestic travel when such travel is not included in the approved budget and for cumulative expenditures for domestic travel in any budget period that will cause the amount awarded in the approved budget for such travel to be exceeded by \$500 or 25 percent of the budgeted amount, whichever is greater.
4. Each single contract for the procurement of general support services, including procurement of equipment and supplies, that will result in a charge of \$25,000 or 10 percent of the total approved direct cost budget, whichever is greater.
5. General-purpose equipment not to exceed \$1,000 per unit.
6. Foreign travel (each separate foreign trip).
7. Insurance on Federal Government-owned equipment.
8. Public information service costs (news releases).
9. Publication and printing costs not to exceed

\$20,000 for a single publication.

10. Self-insurance program (contributions to a reserve fund).
11. Alteration and renovation expenditures not to exceed \$5,000 in a budget period.
12. Audiovisual materials—the cost of acquisition or production not to exceed \$20,000 for a single audiovisual product.

“Grantees covered by this section must request PHS awarding office prior approval for all other proposed programmatic changes and budgetary actions that require such approval.”

Page 46-47—*Change of Grantee Organization*—At the top of page 47, strike the phrase “and may only be accomplished competitively.”

Page 50—*Patents and Inventions*—This section is expanded to read as follows:

“HHS’s regulations on patents and inventions arising out of activities assisted by a grant are set forth in 45 CFR Parts 6 and 8. The HHS patent regulation at 45 CFR Part 8 is under revision. Until a revised Part 8 is issued, OMB Circular No. A-124 (Patents—Small Firms and Nonprofit Organizations), effective March 1, 1982, shall take precedence over any conflicting provisions of the existing HHS patent regulation.”

Page 51—*Procurement*—The following changes are made in the second paragraph:

- In order to indicate that nongovernmental recipients also must make positive efforts to use woman-owned business firms in the procurement of goods and services, the end of the first sentence is expanded to read “use small business concerns, minority-owned businesses, and woman-owned businesses as sources of such goods or services.”
- The citations on the seventh line now read “13 CFR Part 121 and 41 CFR 1-1.701-1.”
- In the third sentence, the phrase “with less than 500 employees” has been deleted. The general guidance intended by this sentence should not include such a standard.
- The citation 41 CFR 1-1.1303 is added to help define a “minority-owned business enterprise.”
- Finally, at the end of the paragraph, the following definition of a woman-owned business has been added: “A woman-owned business is a business which is, at least, 51 percent owned,

controlled, and operated by a woman or women."

With the above changes, the paragraph now reads as follows: "In the procurement of goods or services, including consultant services, nongovernmental recipients must make positive efforts to use small business concerns, minority-owned businesses, and woman-owned businesses as sources of such goods or services. For this purpose, "small business" is defined by using the criteria contained in 13 CFR Part 121 and 41 CFR 1-1.701-1. Generally, if no standard for an industry's field of operation is provided in the regulations, "a small business concern" means an independently owned and operated business that is not dominant in its field of operation. Such a concern may include, but is not limited to, an individual, a partnership, a corporation, a joint venture, an association, or a cooperative. In addition, the concern must make a significant contribution to the U.S. economy through payment of taxes and/or use of American products, materials, and labor. A "minority-owned enterprise," as described in 41 CFR 1-1.1303, is a business, at least 50 percent of which is owned by minority group members, or in the case of a publicly owned business, at least 51 percent of the stock of which is owned by minority group members. A "woman-owned business" is defined as a business which is, at least, 51 percent owned, controlled, and operated by a woman or women."

Page 51—Procurement—Recently a series of equipment control reviews have been conducted by (a) the Inspector Generals of several departments under an initiative approved by the President's Council on Integrity and Efficiency and by (b) the President's Private Sector Survey on Cost Control. Those reviews revealed a failure on the part of a number of grant recipients to comply with the governmentwide requirement providing that grantee procurement actions follow a procedure to assure the avoidance of purchasing unnecessary or duplicative items. Consequently, we find it necessary to highlight that particular requirement by adding the following paragraph to this section:

"Grant recipients must assure that their procurement procedures include a property management/identification capability to avoid the purchase of unnecessary or duplicative items. The basis for this requirement is Attachment 0 (Procurement Standards) of OMB Circular A-102, which is applicable to governmental grantees, and Attachment 0 (Procurement Standards) of OMB Circular A-110, which is applicable to nongovernmental grantees. (See 45 CFR 74.161.)"

Page 52—Contracts for General Activities—Because this item is now subject to an Institutional Prior Approval System, in accordance with the revisions to page 45, the requirement for PHS prior approval applies only to certain types of grantee organizations.

Page 56—Suspension, Termination, and With holding—Delete the last sentence of the second paragraph and substitute the following sentence: "Where a noncompeting continuation award is denied (withheld) because the grantee failed to comply with the terms of a previous award, such a determination may be appealed by the grantee—but only under the HHS grant appeals procedures."

Delete the last sentence of the third (and last) paragraph.

Page 57—Grant Appeals Procedures—The following information, although somewhat duplicative, is designed to clarify the existing material on this subject.

- Because the scope (jurisdiction) of the PHS Grant Appeals Board (42 CFR 50, Subpart D) differs from that of the HHS Grant Appeals Board (45 CFR 16) in several respects, there are not always two levels of appeal available to grantees.
- The scope of the PHS Board is limited to discretionary project programs and, as stated on page 57, the PHS Board reviews the following adverse administrative determinations:
 1. Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance, or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
 2. A determination that an expenditure not allowable under the grant has been charged to the grant, or that the grantee has otherwise failed to discharge its obligation to account for grant funds.
 3. The disapproval of a grantee's written request for permission to incur an expenditure during the term of a grant. (The failure of a PHS awarding office to respond to such a request within 30 days of the postmark date of the grantee's request shall be considered a disapproval.)
 4. A determination that a grant is void.

- The HHS Board covers disputes under mandatory grant programs as well as disputes under discretionary project programs. With respect to the latter category, the HHS Board reviews the following adverse administrative determinations:

1. A disallowance or other determination denying payment of an amount claimed under an award, or requiring return or set-off of funds already received. This does not apply to determinations of award amount or disposition of unobligated balances, or selection in the award document of an option for disposition of program-related income.
2. A termination for failure to comply with the terms of an award.
3. A denial of a noncompeting continuation award under the project period system of funding where denial is for failure to comply with the terms of a previous award.
4. A voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

Page 58—*Debt Collection*—This section is modified to read as follows:

“The Federal Claims Collection Standards (4 CFR Parts 101-105) require that, except where prohibited by law, PHS charge interest on all delinquent debts owed to PHS by grantees. Debts are considered delinquent 30 days after notification to the grantee of the indebtedness. The interest will be computed at the prevailing interest rates issued by the Department of the Treasury. Penalties and administrative costs of collection shall also be charged to grantees other than State and local governments, in accordance with the Debt Collection Act of 1982. The date from which interest is computed is not extended by the filing of an appeal.

“Should a grantee appeal a monetary adverse determination through 42 CFR Part 50, Subpart D and/or 45 CFR Part 16, collection will be suspended pending a final decision on the appeal. If the determination is sustained (either fully or partially) interest will be charged.”

Page 60—*PHS Awarding Offices*—The following changes should be noted:

- Under the Office of the Assistant Secretary for Health, there are three awarding components— as follows:

“National Center for Health Services Research
5600 Fishers Lane
Rockville, Maryland 20857

Office of Disease Prevention and Health Promotion
330 C Street, S.W.
Washington, D.C. 20201

Office of Population Affairs
330 Independence Avenue, S.W.
Washington, D.C. 20201”

- Under the Centers for Disease Control, the National Institute for Occupational Safety and Health should be deleted.
- In the second column, the Health Resources and Services Administration is comprised of the following four awarding components:

“Bureau of Health Professions
5600 Fishers Lane
Rockville, Maryland 20857

Bureau of Health Maintenance Organizations and Resources Development
5600 Fishers Lane
Rockville, Maryland 20857

Bureau of Health Care Delivery and Assistance
5600 Fishers Lane
Rockville, Maryland 20857

Indian Health Service
5600 Fishers Lane
Rockville, Maryland, 20857”

Page 75—*Requirements for Federally Assisted Construction Contracts*. . .—In the second line of the introductory sentence, the word “or” should be “on.”

Page 81—*Appendix IV*—Reference in the chart to “Appendix B” should instead read “Appendix II.”

Page 90—*Policies Governing Federal Grantees*—Add the following new paragraph after the paragraph on “ALLOWABILITY OF COSTS.”

“SALARIES

No salary or fringe benefit payments may be made from PHS grant funds to career, career-conditional, or other Federal employees (civilian or military) with permanent appointments provided for under existing position ceilings of a given Federal component. Temporary employees specifically hired to assist in the conduct of a sponsored PHS assistance program may, if authorized by the grant award, be reimbursed from grant funds.”

Page 90—*Policies Governing Federal Grantees*—The section entitled “PRIOR APPROVAL AUTHORITIES” should be deleted. Readers are directed to page 45 (as revised by this addendum) for guidance on the establishment and use of an Institutional Prior Approval System by Federal grantees.

Page 92—*Grants to For-Profit Organizations*—In the last sentence of the second paragraph, delete the word “research” to indicate that for-profit organizations are eligible for grants for purposes other than research—as well as for research grants. Similarly, the word “research” in the second line of the fourth paragraph should be deleted.

Page 92—*Grants to For-Profit Organizations*—Under item 4, the citation in the last sentence should read “Chapter 38 of Title 35 U.S. Code.”

Page 92—*Grants to For-Profit Organizations*—An item 6 should be added as follows:

“6. Prior Approval Authority—For-profit organizations must obtain prior approval from the Grants Management Officer of the PHS awarding office for all proposed programmatic changes and rebudgeting actions for which prior approval is required.”

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NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 8, June 29, 1984

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JUL 10 1984

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

HEARINGS ON PROPOSED PHS POLICY ON HUMANE CARE AND
USE OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

P.T. 34; K.W. 0201011, 1014002

In the April 5, 1984 Special Edition of the NIH Guide for Grants and Contracts (Vol. 13, No. 5) the Public Health Service (PHS) published a proposed Policy on Humane Care and Use of Animals by Awardee Institutions. Written public comment on the proposed policy was requested and it was announced that the PHS intends to hold three open hearings to give the public an opportunity to make oral comments on the proposed changes and requirements.

The schedule for the hearings will be as follows:

July 19, 1984

Federal Office Building
Room 140
601 East 12th Street
Kansas City, Missouri

July 24, 1984

John F. Kennedy Federal Building
Government Center
Room 2003
Boston, Massachusetts

August 2, 1984

Third and Broad Building
2901 Third Avenue
Room 180
Seattle, Washington

All hearings will convene at 9:00 a.m. and will be open to the public, subject to the limitation of available space. Any person wishing to speak at a hearing should file a written request and receive prior confirmation from the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). Requests to speak will be granted on a first-come, first-served basis. Copies of presentations may be submitted for the record. Oral presentations will be limited to ten minutes. Requests to speak at hearings should be received at least ten days prior to the hearing at the following address:

Ms. Carol Young
Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

84-CA-09

METABOLISM AND PHYSIOLOGY OF RETINOIDS AND CAROTENOIDS IN HUMANS

P.T. 34; K.W. 1200780, 0202022, 1200400, 1007009

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: August 10, 1984
Application Receipt Date: October 5, 1984

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support research on human metabolism and physiologic effects of retinoids and carotenoids. Studies of interest include metabolism in the intestinal mucosa, intestinal absorption, regulation of gastrointestinal uptake and tissue concentrations, and extra-intestinal metabolism of these compounds. The studies should span a range of dietary intakes from RDA levels to levels suspected of being toxic. The proposed research requires innovative approaches to determine the dynamics of absorption and metabolism, target tissue levels, and specificities of the various vitamin A compounds and how these determinations would elucidate the roles of dietary retinoids and carotenoids in cellular integrity and resistance to tumor promotion.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. As more completely described later in this announcement, the recipients will have primary responsibility for the development and conduct of the research. NCI involvement will be in regard to coordinating and synthesizing the research effort in regard to approaches, methodologies and exchange of information.

Copies of the complete Request for Applications and additional information may be obtained from:

Elaine Lanza, Ph.D.
Diet and Cancer Branch
Blair Building - Room 617
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 427-8753

To ensure their review, applications should be received by October 5, 1984.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-14

INVOLUNTARY EXPOSURE TO TOBACCO SMOKE AND CANCER RISK

P.T. 34; K.W. 1002014, 0701013, 1007003, 1007005

NATIONAL CANCER INSTITUTE

Application receipt date: October 15, 1984

I. BACKGROUND

In recent years some epidemiological studies have indicated an association between involuntary or passive smoking and an increased risk for cancer. The reactions to brief exposure to tobacco smoke in enclosed environments range for the nonsmoker from slight irritation of the eye to serious allergic reaction. The reaction usually disappears following a period free from exposure to tobacco smoke. Also reported is a dysfunction of small airways in nonsmokers chronically exposed to tobacco smoke. It has also been reported that nonsmoking subjects of either sex whose spouses were current smokers of at least 10g of tobacco a day had significantly lower forced mid-expiratory flow rate than those married to nonsmokers.

Many chemical substances of mainstream smoke have been reported in sidestream smoke, with some substances released into the sidestream smoke in markedly higher amounts than into the mainstream smoke. The actual absorption of individual smoke components by nonsmokers in smoke-filled environments has been reported only for a few components. The pattern of involuntary inhalation of tobacco smoke is probably different from that of voluntary inhalation by the smoker. This difference would influence the site of deposition and absorption of smoke constituents in nonsmokers compared to active smokers. Therefore, the question arises whether a person exposed involuntarily and for many years to the smoke of others inhales sufficient amounts of carcinogens to elicit a carcinogenic response.

In recent years, a number of epidemiologic studies have been carried out to examine the influence of long-term involuntary exposure to cigarette smoke in nonsmoking women. A large prospective study in Japan reported a significant increase in lung cancer risk among nonsmoking wives of smoking husbands compared with nonsmoking wives of nonsmoking husbands. Wives of husbands who smoked had a two-fold excess of cancer mortality compared to wives of nonsmoking husbands, with suggestive evidence of a dose-response relationship. A recent update of this study also reported an increased risk of cancer of the paranasal sinuses in nonsmoking wives of smoking husbands.

Two case-control studies, one from Greece and the other from the U.S., supported the findings of the Japanese study. However, an analysis of prospective data from the American Cancer Society failed to show a statistically significant association between passive smoking by wives of smoking husbands and lung cancer mortality. This discrepancy may be partly due to differences in methodology of the two prospective studies, or differences between countries in the patterns of involuntary exposures to tobacco smoke. A study carried out in Hong Kong also did not find a relationship between husbands' smoking status and cancer risk among working environment were not taken into account.

A case-control study from the U.S. reported that heavy smoking by wives may increase the lung cancer risk of the light-smoking husband, but smoking by husbands did not significantly affect the risk in women who smoked. Moreover, it was noted that the smoking behavior of the mother, but not that of the father, influenced the lung cancer risk of offspring who smoked. Differences in the histologic distribution of tumors in active smokers and those involuntarily exposed suggest that the differences in physicochemical nature and absorption of mainstream smoke and sidestream smoke may produce different proportions of histological types of tumors.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to stimulate research to assess the effect of involuntary exposure to tobacco smoke on cancer risk. Research of interest includes, but is not limited to (1) studies designed to quantify involuntary exposure to tobacco smoke. For example, the development and field testing of a questionnaire designed to measure involuntary exposure to tobacco smoke, with subsequent validation by appropriate means, (2) ad hoc refinement or modification of existing epidemiologic studies by addition of questions relating to involuntary smoke exposure, and (3) development of case-control studies of tobacco-related cancers in settings that lend themselves specifically to evaluation of the effects of involuntary tobacco smoke exposure.

III. INQUIRIES

Inquiries may be directed to:

Dr. A.R. Patel
Extramural Programs Branch
Epidemiology and Biostatistics Program
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 8C-16
Bethesda, Maryland 20205

Telephone: (301) 496-9600 (9601, 9602 or 9603)

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-16

BASIC RESEARCH IN FACTORS INFLUENCING NUCLEAR MAGNETIC RESONANCE

(NMR) RELAXATION TIMES IN BIOLOGICAL TISSUES

P.T. 34; K.W. 1013034, 1200380, 1013004, 1003002, 1013020, 1002021

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1984

I. BACKGROUND

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites investigator-initiated research grant applications for basic studies to elucidate quantitatively the factors and mechanisms which influence and determine the T_1 and T_2 NMR relaxation times in in vitro systems and normal and abnormal mammalian tissues.

Rapid progress has been made over the past several years in the development of new NMR imaging and spectroscopic techniques for research and diagnostic applications. There is a special need for a more scientific understanding of the imaging and tissue characterization information that is generated by these NMR systems.

The interdisciplinary nature of this study will require some combination of expertise included in, but not limited to, the areas of nuclear magnetic resonance phenomena; biophysics and biochemistry at molecular, cellular, tissue, organ, and whole body levels; in vitro cell and tissue cultures; histopathology; animal and/or human physiology and pathology; and a probable variety of additional disciplines and instrumentation techniques as needed to study the complex substances and phenomena that are involved.

II. GOALS AND SCOPE

The objective is to encourage creatively designed, basic experimental studies of the properties of biological materials and tissues in magnetic fields and of the physical

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

and biological phenomena which influence and determine the T_1 and T_2 NMR relaxation times. The ultimate purposes of acquiring this knowledge are potentially to permit definitive noninvasive characterization of tissues by NMR and to enhance the abilities of NMR clinicians of the future to obtain superior imaging and tissue characterization information and to interpret its diagnostic significance.

The scope of studies needed to gain the insight desired will be determined by the ingenuity of the investigator and the experimental approach and will be limited principally by the bounds of reasonable cost. It may be limited to certain specific aspects of the problem or it may include a wide variety of sub-projects ranging from molecular to whole organism studies. The complex biochemical nature of tissues suggests that fundamental studies of some simple in vitro and in vivo systems will be required to establish the basis for understanding more complicated biological systems. Proof of the knowledge achieved might eventually be demonstrated by obtaining quantitatively predictable NMR results in controlled scientific experiments with living tissues or in simpler systems.

III. MECHANISM OF SUPPORT

Applicants funded under the RFA will be supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with all PHS policies applicable to Research Grants, including cost sharing. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should be typically three years as a balance between the long-range nature of this type of research and the exploratory character of the studies at this stage of development. Studies should not be proposed to exceed five years. The intent is to fund approximately four to eight projects, with total program costs for all grants under this RFA equal to approximately \$750,000 of FY 85 funds for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is included in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose. The issuance of this RFA does not represent a guarantee that any funds will be awarded. No funds are available for the purchase of a large cost capital equipment.

The present RFA announcement is for a single competition with a specified deadline of November 15, 1984, for receipt of applications.

IV. COPIES OF THE RFA MAY BE OBTAINED FROM:

Mr. Roger S. Powell
Program Director
Diagnostic Imaging Research Branch
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
Landow Building - Room 8C09
Bethesda, Maryland 20814

Telephone: (301) 496-9531

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

AI-84-08

SEXUALLY TRANSMITTED DISEASES RESEARCH UNIT

P.T. 34; K.W. 1201360, 1200670, 1200410, 1200370, 0701013, 0701042, 0415000,
1004005, 1002027

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 15, 1984

I. BACKGROUND INFORMATION

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for a program project grant to be initiated during FY 1985 for participation in an ongoing program of research in Sexually Transmitted Diseases (STD). This RFA will not be reissued in fiscal year 1985.

One of the major health problems in the U.S. today is that of sexually transmitted (venereal) diseases. The explosive rise in gonococcal infections in the last decade, for example, with an estimated 2,000,000 gonococcal cases per year, can be considered a major infectious disease epidemic. Many other diseases, such as chlamydial infections, genital herpes, enteric infections, and hepatitis B, are known to be transmitted by the sexual route; these are now being recognized with increasing frequency. Pelvic inflammatory disease, the most serious sequela of gonococcal and chlamydial infection in females, costs the health services an estimated \$1.25 billion annually.

II. RESEARCH GOALS AND SCOPE

- A. As one means of achieving the major goal of further needed research in this area, the NIAID proposes to maintain support of a number of STD research units, or centers of excellence, to serve as foci for research and training in STD. This RFA is for support of one such STD unit; these units are funded as multidisciplinary program project grants. A strong clinical component should be a major part of the application, with individual investigators heading separately identifiable research subprojects within the overall cover of the program project. The fields of research to be considered for emphasis in this program project can be on any or all of the STDs that are currently recognized as significant public health problems.
- B. The research efforts will focus on diseases known, or believed to be transmitted by sexual contact or the sexual route. The diseases of interest in this program are: gonorrhea; syphilis; chlamydial infection; trichomonas

infection; viral infections such as genital herpes, genital warts, hepatitis B; nonspecific vaginitis; enteric diseases; parasitic infestations. Specific areas of research can include: basic biology and virulence factors of the causal organism; the hosts' immune responses; animal model systems; diagnosis, therapy, and preventive measures; epidemiology, including computer modeling studies.

An educational component to advance learning experiences in STD of medical staff and fellows, as well as a community outreach program, can be considered an appropriate part of the STD Research Unit.

C. Mechanism of Support

Eligibility - domestic universities, medical colleges, hospitals, and laboratories of public or private institutions are eligible.

The program project (STD Research Unit) can be supported for up to five years; renewability is dependent on successful competition and the availability of funds. Earliest start date is July 1, 1985. This request is an open competition; one currently funded STD Research Unit is competing for renewal support.

III. IDENTIFICATION OF CONTACT POINT

Direct inquiries and requests for the full text of the RFA to:

Milton Puziss, Ph.D., Chief
Bacteriology and Virology Branch
MIDP
National Institute of Allergy and
infectious diseases
National Institutes of Health
Westwood Building - Room 738
Bethesda, Maryland 20205

Telephone: (301) 496-7728

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HD-05

INTRAUTERINE GROWTH RETARDATION - PERINATAL EMPHASIS RESEARCH CENTER

P.T. 34; K.W. 1201040, 1201070, 1200370, 1201270, 1002019, 0607024, 0701005

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 15, 1984

The Pregnancy and Perinatology Section of the Clinical Nutrition (CNPP) and the Early Development Branch of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites grant applications (P-50) for a Perinatal Emphasis Research Center (PERC) focused on intrauterine growth retardation (IUGR).

The PERC's are organized around problem/need themes and are established where research can be coordinated with existing programs of health care to insure the rapid assimilation of new scientific knowledge into health care delivery. PERC's are located throughout the United States and presently are addressing issues in high risk pregnancies (diabetes, hypertension), prevention of prematurity, and fetal hypoxia.

I. RESEARCH GOALS AND SCOPE

This PERC is proposed to deal with promising research areas in IUGR. They include etiologic mechanisms, improvement of diagnostic techniques, and various aspects of prevention and management of IUGR. Investigators are invited to propose studies with a significant clinical component encompassing a wide spectrum of normal and abnormal fetal growth and development as well as fetal-maternal interactions. Supported research may be done with patients or in experimental animals. Studies are encouraged on embryogenesis, cell proliferative growth, and organogenesis as well as on such factors as "specific limiting substances" which may control intrauterine development and/or serve as markers

This program is described in the Catalog of Federal Domestic Assistance No. 13.865 Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

of development. Investigations on the genetics or the influence of viral infections and teratogens that may restrict cell proliferation and fetal growth also would be appropriate. Studies may focus on the placenta as it may affect IUGR. Factors affecting the availability of nutrients or substrates to the fetus offer another area of considerable interest, both in terms of placental function and fetal response to these factors or substrates. Another important area concerns improved methods for assessing fetal health and development and for early detection of developmental anomalies. These may include safety studies on ultrasound or nuclear magnetic resonance as well as a wide variety of biochemical markers for adequacy of fetal growth, growth retardation, or congenital anomalies. Correlation of these indicators with pre-natal conditions and post-natal development would be important. Research also is needed on the most suitable methods for managing IUGR infants so as to maximize infant growth, health, and development.

II. ELIGIBILITY

Domestic non-profit organizations and institutions are eligible to apply.

III. MECHANISM OF SUPPORT

Perinatal Emphasis Research Center grants (P-50) will be supported through the customary grant-in-aid mechanism.

IV. ESTIMATED NUMBER OF AWARDS

This is a one-time announcement with plans to make one award in fiscal year 1985.

V. OFFICE WHERE FULL RFA MAY BE OBTAINED

A complete Request for Applications entitled "Intrauterine Growth Retardation" and guidelines concerning "NICHD Research Center Programs" may be obtained from:

Dr. Charlotte Catz
Head
Pregnancy and Perinatology Section
Clinical Nutrition and Early
Development Branch
Center for Research for Mothers and
Children
National Institute of Child Health
and Human Development
Landow Building - Room 7C09
Bethesda, Maryland 20205
Telephone: (301) 496 5575

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HD-06

ACCEPTABILITY AND UTILIZATION OF THE CONTRACEPTIVE SPONGE

P.T. 34; K.W. 0413002, 1200320, 0701014, 1002034, 1200180, 0404000

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: November 15, 1984

I. PROGRAM OBJECTIVES

The Demographic and Behavioral Sciences Branch (DBSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), has a high degree of interest in the antecedents and consequences of fertility and fertility regulation. The RFA invites scientists to submit grant applications for the support of research on the acceptability, utilization, and effectiveness of the contraceptive sponge. Scientists have an unusual opportunity to conduct research on the contraceptive sponge while it is in the relatively early stages of its use. Investigators will be able to analyze the progress of this method as it becomes part of the armamentarium of fertility regulating methods. Analysis and evaluation of this method in comparison with other contraceptive methods will enhance the scope and implications of the research. Multidisciplinary or unidisciplinary investigations may be conducted. Comparative, crosscultural, transnational or historical approaches may be utilized. Investigators may use extant data, new data, or a combination of both. Appropriate statistical methods, including life table techniques, may be employed. The following questions are among those which the research may be designed to answer. How many contracepting and non-contracepting women are switching to the sponge or using it as their initial contraceptive? What are the factors that influence some women to adopt a relatively new method? Does the sponge have special appeal for women in groups that have a high risk of unintended pregnancy? How do women perceive the sponge in terms of its possible positive and negative effects on health and the role it might play in relation to sexually transmitted diseases? What factors encourage the use of the contraceptive sponge? What factors, such as somatic complaints and other side effects, discourage the use of the sponge?

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

II. MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA). Copies of the complete RFA may be obtained from:

Sidney H. Newman, Ph.D.
Demographic and Behavioral Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - ROOM 7C25
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

CLINICAL STUDIES OF THE EFFECT OF LITHIUM AND PHENYTOIN

IN VIOLENT PATIENTS

P.T. 34; K.W. 1200280, 0404023

FOOD AND DRUG ADMINISTRATION

Application Receipt Date: October 1, 1984

SUMMARY

The Food and Drug Administration (FDA), Office of Orphan Products Development (OPD) is announcing the availability of funds for Fiscal Year 1985, for awarding a grant(s) to support a randomized double-blind placebo-controlled study of lithium and phenytoin in adult patients who manifest episodes of extreme violence and aggressiveness. FDA has approximately \$250,000 available to award a grant(s) to support this research in Fiscal Year 1985. FDA anticipates that one or two awards will be made. Support for this program may be for a period of up to three years.

Applications must be received by October 1, 1984. The earliest date for award is February 1, 1985.

A Request for Application (RFA) is to be published in the Federal Register in June announcing the details.

In order to receive a copy of the RFA, and further information, contact:

Benjamin P. Lewis
Health Scientist Administrator
Office of Orphan Products Development
FDA/HF-35
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENTAVAILABILITY OF REQUESTS FOR APPLICATIONS: (RFA)84-HL-15-BSPECIALIZED CENTERS OF RESEARCH IN THROMBOSIS/NATIONAL RESEARCH ANDDEMONSTRATION CENTER IN THROMBOSIS NIH 84-HL-15-B

P.T. 34, 04; K.W. 1200230, 1200240, 1200180, 1200370, 0701042, 0415000, 0403004

DIVISION OF BLOOD DISEASES AND RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date February 15, 1985

The Division of Blood Diseases and Resources (DBDR) of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH) supports a comprehensive research program in thrombosis and hemostasis. This comprehensive research program is intended to be a multidisciplinary approach directed at expediting the development and application of new knowledge essential for improved diagnosis, treatment, and prevention of hemostatic disorders. As part of this comprehensive program, the NHLBI announces competition for Specialized Centers of Research (SCOR) in thrombosis and for National Research and Demonstration Centers (NRDC) in thrombosis. Applications received in response to this request will participate in a single competition. A NRDC in thrombosis is conceived as an enhancement of the SCOR program. It must include basic and clinical research (the traditional SCOR components) along with demonstration and education research and an essential coordinating and integrating effort. Applicants may apply for either a NRDC or a SCOR. The submission of a NRDC application may, in some instances, result in the award of a SCOR grant. In other words, the applicant institution may apply for support as a NRDC but, after appropriate peer review, it may be approved only as a SCOR if the other components (demonstration and education research and integration) are significantly weaker.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 74. This program is not subject to Health Systems Agency review.

The requirements and formats for applications submitted in response to this announcement and additional information regarding the characteristics of these mechanisms of support can be obtained from:

Anne P. Ball, Ph.D.
Chief, Blood Diseases Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5A12
Bethesda, Maryland 20205

Telephone: (301) 496-5911

SUMMARY OF SELECTED CAREER DEVELOPMENT AWARDS

The following four announcements describe some of the mechanisms employed by the National Institutes of Health (NIH) to encourage the development of research investigators. The first, the Dentist Scientist Award (DSA), is a new mechanism introduced by the National Institute of Dental Research (NIDR). Its purpose is to provide opportunities for dentists with a strong commitment to oral health research to develop into independent biomedical investigators. Although specially tailored to the experience and capabilities of dentists, it is similar in most respects to the Physician Scientist Award (PSA) initiated in July 1983 by several NIH Institutes, including NIDR.

The second announcement is a reissuance, with minor modifications of the PSA.

The third announcement invites applications for the Clinical Investigator Award (CIA). As explained in the announcement, the CIA differs from the PSA, intended for newly-trained physicians, and the Research Career Development Award (RCDA), aimed at junior faculty members who have demonstrated research potential. This announcement includes minor modifications in this award.

Changes of special interest to investigators seeking CIA funds from the National Institution of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDDK) appear in the fourth announcement.

The table on the following page summarizes the major features of the CIA, PSA, and RCDA.

	CLINICAL INVESTIGATOR AWARD	PHYSICIAN SCIENTIST AWARD	RESEARCH CAREER DEVELOPMENT AWARD
Purpose	To prepare clinical investigators who have had some research experience for independent research careers	To provide clinicians who have had essentially no research experience for independent research careers	To support further development of junior faculty by allowing maximum effort to be spent in research
Eligibility	Clinical degree	Clinical degree	Training completed
Clinical Experience	Normally have finished clinical training	May have had only one year clinical training	N/A
Research Experience	Yes	Normally no	Yes
Sponsor Requirement	Yes	Yes	No
Sponsor Salary Support	No	Yes, for Phase I	N/A
Salary Support	Up to \$40,000 plus commensurate fringe benefits	Up to \$40,000 plus commensurate fringe benefits	Up to \$40,000 plus commensurate fringe benefits
Research Support Included	Yes	Yes	No; holder normally holds a research project grant
Duration of Award	5 years	5 years	5 years
Indirect Cost	8%	8%	8%

ANNOUNCEMENTDENTIST SCIENTIST AWARD

P.T. 34; K.W. 0701012, 1200180

NATIONAL INSTITUTE OF DENTAL RESEARCH

Initial Application Receipt Date: October 1, 1984
Subsequent Receipt Dates: February 1, June 1, October 1

The National Institute of Dental Research (NIDR) announces the availability of the Dentist Scientist Award (DSA). The DSA is specifically designed to provide opportunities for dentists with a strong commitment to oral health research to develop into independent biomedical investigators. Two forms of the award are available: the program award and the individual award.

This award will enable dentists to undertake five years of study to prepare for careers in oral health research. There are three distinct but overlapping and integrated components to the DSA: advanced basic science development, advanced clinical science development, and a supervised research experience. The advanced basic science development component is designed to develop knowledge and research skills in basic science areas relevant to dentistry. This component will include both didactic and laboratory experiences in a fundamental science. This will most typically consist of a doctoral level program, e.g., Ph.D., Sc.D., provided that the respective institution's degree requirements are consistent with the objectives of the DSA. The advanced clinical science development component is to ensure that the candidate has requisite advanced knowledge and skills in a recognized clinical speciality or other appropriate dental clinical discipline. The research experience component is designed to facilitate transition to an active research career. This component requires a research program plan using a basic science or clinical five-year research development program each candidate will require the close sponsorship of an individual mentor with an extensive research background.

The purpose of the DSA is the development of competent dental clinical scholars for research careers. Candidates will be limited to those dentists prepared to make a serious career commitment to dental science and who demonstrate high research potential.

Institutions and individuals wishing complete details on eligibility, mechanisms of award, application procedures and review criteria should contact:

Thomas M. Valega, Ph.D.
Special Assistant for Manpower Development
Extramural Program
National Institute of Dental Research
Westwood Building - Room 510
Bethesda, Maryland 20205

Telephone: (301) 496-7807

ANNOUNCEMENT

PHYSICIAN SCIENTIST AWARD

P.T. 34; K.W. 1200180, 1200270

NATIONAL INSTITUTE ON AGING*
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES*
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES*
NATIONAL EYE INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Institutes of Health (NIH) announces the availability of the Physician Scientist Award to be supported by those institutes listed. The award is intended to encourage newly trained clinicians to develop independent research skills and experience in a fundamental science. The PSA is targeted to newly trained clinicians who wish to receive training in a basic scientific discipline for application to a research problem that may not yet be well defined.

These awards provide the opportunity for clinically trained professionals with a commitment to research to develop into independent biomedical investigators. Two types of awards are available: the program award and the individual award.

The awards will enable individuals with clinical training to undertake up to five years of special study in basic science with a supervised research experience. The first phase (two to three years) of the program will include both didactic study and laboratory experience conducted under the close sponsorship of an individual with extensive research experience in fundamental sciences. The second phase (up to three years) under the continuing guidance of this primary sponsor, will be to apply laboratory-based research in either a basic science or clinical department. This award requires a commitment from a sponsor with extensive fundamental research experience in a basic science such as (but not limited to) biochemistry, molecular biology, genetics, or immunology, and a research program plan using a fundamental or clinical science approach to disease related problems.

In summary, the Physician Scientist Award is designed to encourage the individual with clinical training to develop research skills in a fundamental science. To help support the transition from clinical training status to that of a productive investigator able to compete successfully for NIH research support, the Physician Scientist Award will provide the opportunity for clinicians to develop into independent investigators, to obtain research experience under the sponsorship of a basic research scientist and to initiate a research program.

* These three institutes offer the individual and the program award. The remaining institutes offer the individual award only.

I. ELIGIBILITY

- A. These awards are designed to provide an intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health professional degrees in the clinical sciences (M.D., D.D.S., D.V.M., D.O. or equivalent). Ordinarily physicians holding the PhD are ineligible. Exceptions may be made to this requirement (1) for individuals with Ph.D.s unrelated to the biomedical and behavioral sciences or (2) for those who were involved in other than research activities after receipt of the Ph.D. where the elapsed time was such as to require two or more years of development to update basic science skills. Candidates ordinarily will have completed at least one post-graduate year of clinical training by the time the award is made.
- B. Candidates should demonstrate competence in clinical activities, and should show research potential. Candidates must provide evidence of a serious intent for research and academic careers.
- C. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.
- D. Applicants for a Physician Scientist Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, a Clinical Investigator Award or a Special Emphasis Research Career Award. Physician scientist awardees may subsequently apply for a New Investigator Research Award or a research project grant.
- E. Ordinarily a candidate with previous independent NIH research support or its equivalent will not qualify.

II. MECHANISMS OF AWARD

This award may be supported through two mechanisms: the individual award and the program award.

A. Individual Awards

1. The Environment

Applications will be accepted from a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic sciences and commitment and capability to provide guidance to clinically trained individuals in the development of independent research careers. The environment desired is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for

a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided.

2. The Program

The individual's program should be designed in two phases. The candidate must provide a description of the research development plan. It should start with a creative and detailed basic science learning experience in Phase I and progress to culminate in intensive research activity in Phase II under the general guidance of a qualified sponsor. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed Phase II research plan and protocol for administrative review and approval.

3. Sponsor

Each candidate must identify a primary sponsor who is recognized as an accomplished investigator in the basic science research area proposed, who has experience in training independent investigators and who will provide the guidance for the awardee's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

4. Duration and Effort

This five year non-renewable award is based on up to five full-time 12 month appointments. All funds must be used on behalf of the original candidate. Support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. It is required that a minimum of 75 percent effort be devoted to the research and research training program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator or necessary to maintain clinical skills necessary for an academic clinical career.

It is desirable for individuals to complete both phases without interruption. It may be permissible, however, to interrupt the award and delay the start of Phase II in order to engage in further clinical training. In the event such a contingency arises, the awardee and the sponsor must justify the interruption to the awarding institute to assure that funds will be available to resume the award so that the candidate may complete the program.

5. Allowable Costs

- a. Salary -- Individual compensation based on the institution's salary scale for residents or junior faculty at an equivalent experience level but funding from this award for salary not to exceed \$40,000

per year per individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.*

- b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.
- c. Research and Development Support -- \$10,000 per year in Phase I increasing to \$20,000 per year in Phase II for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.
- d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

6. Concurrent Awards

Individuals entering Phase II are encouraged to apply for additional research support, e.g., New Investigator Research Award (R23) or Research Project award (ROI). Such support may be applied for and held with no reduction in the \$20,000 provided as research support. However, salary support from PHS sources above the \$40,000 provided by this award is not allowable.

- B. Program Award - Institutions with Program Awards may recruit and select candidates into their programs on a local basis rather than submitting a separate application on behalf of each prospective candidate. In all other respects, Program Awards are intended to provide support for the development of physician scientists in the same manner and under the same terms as the individual awards.

1. The Environment

Applications will be accepted from an association of departments and divisions and/or clinical departments representing a range of research interests. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs with adequate numbers of highly trained faculty in clinical and basic sciences and with the interest and capability to provide guidance to clinically trained individuals in the development of research independence. The environment sought is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

2. Program Director

The proposed Program Director should possess the scientific expertise,

* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

leadership and administrative capabilities required to coordinate and supervise an interdisciplinary research and development program of this scope. The Director should also be experienced in the design and management of programs for developing investigators, and should be able to demonstrate a superior record in the preparation of clinical investigators for independent research. In addition, a committee with representatives from the appropriate basic and clinical science departments shall be established to advise the Program Director.

3. Sponsor

Each candidate appointed on the grant must have a primary sponsor who is recognized as an accomplished investigator, actively involved in basic science research who will provide the guidance for the candidate's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

4. Program

The Program award provides five years of renewable support. The award is intended to provide up to five years support of consecutive full-time 12 month appointments to each individual candidate appointed. This support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. The support starts with Phase I which is to be a creative and detailed basic science learning experience and culminates in Phase II which requires intensive research under the general guidance of a qualified sponsor.

It is desirable for individuals to complete both phases without interruption. It is permissible, however, to delay the start of Phase II in order to engage in clinical training. In the event such a delay occurs, it is expected that the program director will plan to provide the necessary resources for the awardee to reenter and complete the program. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular an appropriately detailed Phase II research plan and protocol for administrative review and approval.

5. Duration, Effort and Allowable Costs: Support may be requested for up to two postdoctoral candidates entering Phase I per budget period.

- a. Salary -- Compensation for candidate based on the institution's salary scale for residents at an equivalent experience level but funding from this award is not to exceed \$40,000 per year per

individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.*

- b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.
 - c. Research and Development Support -- \$10,000 per year in Phase I increasing to \$20,000 per year in Phase II per candidate for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.
 - d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.
6. Budgeting for Future Years

Critical to the success of this program award is the ability of the Program Director to make detailed mid-course assessments of each candidate's developing research skill and of the proper time for transition from one phase to another. It is expected that applicant institutions will initiate their activities under this award in a staged manner. That is, the first requested year of support would include funds for candidates in Phase I only. The second year would request funds for new candidates in Phase I as well as for continued funding of the first year's supported individuals. In this way, the requested level of support would increase steadily from the 01 through the 05 budget period as new candidates were appointed.

7. Concurrent Awards

Individuals entering Phase II are encouraged to apply for separate research support. Such support may be applied for and held with no reduction in the \$20,000 provided as research support. However, salary support from PHS sources above the \$40,000 provided by this award is not allowable.

III. EVALUATION

Awardees must agree to inform the National Institutes of Health annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the research grant, awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public

* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

Law 78-410, as amended, 42 USC 241). The regulations (Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH), will prevail.

The award of grants pursuant to this announcement is contingent upon availability of appropriate funds.

V. METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH Division of Research Grants (DRG), and, governed by normal programmatic considerations as specified in the NIH Referral Guidelines, will be assigned to the appropriate institute for possible funding.

Applications in response to the Announcement will be reviewed in nationwide competition, and in accordance with the usual NIH peer review procedures. They will first be reviewed for potential for research development and scientific and technical merit by an institute review group composed mostly of non-Federal scientific consultants (initial review group). Following this review, the applications will be evaluated by the appropriate Institute Advisory Council (IAC).

VI. APPLICATION PROCEDURES

The original and five copies should be mailed to DRG and one copy to the institute contact person. The outside of the envelope should be identified as **PHYSICIAN SCIENTIST AWARD**.

Deadlines for receipt of applications by the Division of Research Grants, NIH, are as follows:

Applications Received by	Presented to Council in	Earliest Requested Beginning Date
February 1	September/October	December 1
June 1	January	April 1
October 1	May	July 1

For further details and in order to obtain an application kit contact the person listed below in the institute offering awards in your area of research interest.

NATIONAL INSTITUTE ON AGING

Edward L. Schneider, M.D.
 Associate Director, Biomedical Research and
 Clinical Medicine, NIA, NIH
 Building 31 - Room 5C11
 Bethesda, Maryland 20205

Telephone: (301) 496-4996

NATIONAL INSTITUTE OF ALLERGY
AND INFECTIOUS DISEASES

John W. Diggs, Ph.D.
Director, Extramural Activities Program, NIAID, NIH
Westwood Building - Room 703
Bethesda, Maryland 20205

Telephone: (301) 496-7291

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES,
AND DIGESTIVE AND KIDNEY DISEASES

Alan Moshel, M.D.
NIADDK, NIH
Westwood Building - Room 405
Bethesda, Maryland 20205

Telephone: (301) 496-7326

or

Walter S. Stolz, Ph.D.
NIADDK, NIH
Westwood Building - Room 657
Bethesda, Maryland 20205

Telephone: (301) 496-7277

NATIONAL INSTITUTE OF CHILD
HEALTH AND HUMAN DEVELOPMENT

Duane Alexander, M.D.
Deputy Director, NICHD, NIH
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) 496-1848

NATIONAL INSTITUTE OF DENTAL RESEARCH

Anthony Rizzo, D.M.D.
Deputy Associate Director for
Extramural Programs, NIDR, NIH
Westwood Building - Room 507
Bethesda, Maryland 20205

Telephone: (301) 496-7748

NATIONAL INSTITUTE OF ENVIRONMENTAL
HEALTH SCIENCES

Christopher Schonwalder, Ph.D.
Scientific Director for Extramural
Training Programs, NIEHS, NIH
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-7634

NATIONAL EYE INSTITUTE

Ronald Geller, Ph.D.
Associate Director for Extramural and
Collaborative Programs, NEI, NIH
Building 31 - Room 6A03
Bethesda, Maryland 20205

Telephone: (301) 496-4903

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Jerome G. Green, M.D.
Director, Division of Extramural Affairs, NHLBI, NIH
Westwood Building - Room 7A17
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENTCLINICAL INVESTIGATOR AWARD

P.T. 34; K.W. 1200180, 1200270

NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY
DISEASES
NATIONAL CANCER INSTITUTE
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: October 1, February 1, June 1

I. PURPOSE

The Clinical Investigator Award (CIA) is designed to provide the opportunity for promising clinically-trained individuals to develop into independent biomedical investigators. It enables candidates to investigate a well-defined problem under a sponsor (or sponsors) competent to provide guidance in the chosen area of research. The award is intended to facilitate transition from postdoctoral training to a career as an independent investigator.

The CIA differs from the Research Career Development Award (RCDA). The RCDA is intended for those who have already demonstrated outstanding potential for contributing, as independent investigators, to health-related research. The CIA and the Physician Scientist Award (PSA) differ from the RCDA in that both are limited to health professionals, and specifically to those that have not had sufficient research experience to demonstrate such potential. The CIA is further targeted to those who have completed their postdoctorate clinical training, have had some research experience, have defined an area of research interest, and are now seeking supervised research experience in a basic or clinical science discipline to further develop their capabilities. The PSA is intended for physicians at an earlier stage of their postdoctoral clinical training who wish to obtain intensive training in a basic scientific discipline for a two to three year period; these individuals may not yet have identified a specific research problem or protocol.

This issuance combines all NIH Clinical Investigator Award announcements that were previously published separately by each Institute. POTENTIAL APPLICANTS ARE ENCOURAGED TO CONTACT THE INDIVIDUAL NIH STAFF MEMBERS WHOSE NAMES ARE APPENDED TO THE MAIN TEXT FOR SPECIFIC DETAILS CONCERNING THE INSTITUTES' SPECIAL AREAS OF INTEREST. Policies and guidelines in this combined announcement become effective for Clinical Investigator Award applications received on or after February 1, 1985. Awards based on applications received prior to that date will be guided by the program announcements and policies in effect at that time.

II. ELIGIBILITY

Applications may be made by institutions on behalf of candidates who hold the M.D. or equivalent degree (D.D.S., D.V.M. or equivalent). Ordinarily those holding the Ph.D. are ineligible. Exceptions may be made to this requirement (1) for individuals with Ph.D.s unrelated to the biomedical and behavioral sciences or (2) for those who were involved in other than research activities after receipt of the Ph.D. where the elapsed time was such as to require two or more years of development to update basic science skills. Individuals who are, or have been, principal investigators on PHS supported research grants or who have, or have had, comparable responsibility for the conduct of a research project, are not eligible. In general, candidates should have no fewer than two years and no more than seven years of postdoctoral experience. (In selected circumstances, these restrictions may be waived, but this will require special justification.) Candidates should provide evidence of a serious intent to enter upon an academic research career. Only U.S. citizens or non-citizens lawfully admitted for permanent residence are eligible.

It is expected that CIA applicants will have completed their clinical training and will have had some postdoctoral research experience before the award is initiated.

The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs in the chosen area, adequate numbers of highly trained faculty in clinical and basic science disciplines, and interest, capability, and commitment to provide guidance to clinically trained individuals in the development of research independence.

III. CONDITIONS OF THE AWARD

Three of the participating Institutes specify a maximum of three years and four offer up to five years of support. (For details, see the Supplemental Instructions.) The award is non-renewable, usually non-transferable, and is based on a full-time (75-100%) research development effort.

The award provides salary support not to exceed \$40,000 annually. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience and rank. Supplementation of salary from non-government sources is allowable. Up to a total of \$10,000 annually may be requested for supplies, equipment, travel, tuition, etc. (In the case of NIADDK, up to \$20,000 may be provided annually for personnel other than the awardee, supplies, travel, equipment, etc.) The indirect cost rate may not exceed 8% of the total allowable direct costs. The grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the salary provided by the Clinical Investigator

Award. Applicants may not hold or apply for research project grants or their equivalent at the time of CIA application, nor may they apply concurrently for a PSA or other type of NIH Academic Award. However, they may apply for, and hold, the regular research project grant or New Investigator Research Award subsequent to award of the CIA.

Candidates must be nominated by an institution on the basis of qualifications, interests, motivation and potential for an academic or research career. The institution should provide evidence of its commitment to the candidate's research development. The candidate's sponsor(s) must provide a description of the development and research plan for the candidate, an updated curriculum vitae with bibliography and research support, and a letter indicating his/her willingness to provide guidance and support for the period of the award. Candidates must provide a full description of the proposed research and career development plan for the period of the award.

IV. REVIEW CRITERIA

Applications for the NIH Clinical Investigator Award will receive initial technical merit review by an initial review committee appointed by the Institute and secondary review by the corresponding Advisory Council or Board.

Criteria for review include:

- A. The candidate's potential for a career in independent research;
- B. The candidate's commitment to a research career;
- C. The overall merit of the candidate's plan for research and the development of research skills;
- D. The quality of the candidate's clinical training and experience;
- E. The institution's ability to provide adequate facilities, resources, and opportunities necessary for the candidate's research development;
- F. The quality of the faculty in the departments relevant to the area of study;
- G. The ability and plans of the sponsor or sponsors who will guide the candidate in his/her career development;
- H. The candidate's conformance to the eligibility requirements; (see Section II of this announcement.)
- I. NIEHS applicants will also be evaluated regarding their plans for development of a clinical research program at their home Institutions.

V. METHOD OF APPLYING

Applications should be submitted on the research grant application (Form 398, Rev. 5/82). If unavailable at the applicant institution's office of sponsored programs, it may be requested from the:

Office of Grants Inquiries
 Division of Research Grants
 National Institutes of Health
 Bethesda, Maryland 20205

Telephone: (301) - -496-7441

Applications for CIA must be received by the NIH for review by the following receipt dates:

<u>Application Receipt Dates</u>	<u>Initial Review</u>	<u>Council Meeting</u>	<u>Earliest Start Date</u>
October 1	Feb/March	May/June	July 1
February 1	June	Sept/Oct	December 1
June 1	Oct/Nov	Jan/Feb	April 1

VI. Research Areas of Emphasis and BID Contacts

National Institute on Aging

Research in Geriatric Medicine
 Organic Brain Diseases of Old Age
 Clinical Nutrition and Aging
 Clinical Immunology and Aging
 Clinical Pharmacology and Aging
 Endocrinology and Aging
 Maturity Onset Diabetes and Aging
 Dermatology and Aging
 Epidemiology and Aging

Inquiries about the program should be directed to:

Don Gibson, D.V.M.
 Associate Director, PEA
 National Institute on Aging
 9000 Rockville Pike
 Bethesda, Maryland 20205

Telephone: (301 - 496-9374

National Institute of Allergy and Infectious Diseases

NIAID supports the development of basic research skills in the fields of immunology, allergy and immunologic diseases, bacteriology, virology, mycology, parasitology, and epidemiology.

Inquiries about the program should be directed to:

Robert Goldstein, M.D.
 Chief, Allergy and Clinical Immunology Branch
 Westwood Building - Room 757
 Bethesda, Maryland 20205

Telephone: (301) - 496-7551
 or

Robert Edelman, M.D.
 Chief, Clinical and Epidemiological Studies Branch
 Building 31 - Room 7A49
 Bethesda, Maryland 20205

Telephone: (301) - 496-5893

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Arthritis, Musculoskeletal, and Skin Diseases
 Diabetes, Endocrine, and Metabolic Diseases
 Digestive Diseases and Nutrition
 Kidney, Urologic, and Blood Diseases

NIADDK limits the CIA to individuals who have had at least two years of previous postdoctoral research training.

Inquiries about the program should be directed to:

Director Division of Extramural Activities
 National Institute of Arthritis, Diabetes, and
 Digestive and Kidney Diseases
 Westwood Building - Room 657
 Bethesda, Maryland 20205

Telephone: (301) - 496-7793

National Cancer Institute

This award is intended to promote research career development in any of the basic and applied sciences relevant to cancer. The NCI is especially interested in the research career development of physicians trained in the following areas:

Surgical Oncology
 Radiation Oncology
 Physiatry
 Preventive Oncology
 Epidemiology and Nutrition

Inquiries about the program should be directed to:

Barney Lepovetsky, Ph.D., J.D.
Chief, Cancer Training Branch
National Cancer Institute
Blair Building - Room 717
8300 Colesville Road
Silver Spring, Maryland 20205

Telephone: (301) - 427-8898

National Institute of Child Health and Human Development

Research on Maternal and Child Health and Reproductive Sciences:

Pregnancy and Perinatology
Congenital Abnormalities
Clinical Nutrition
Reproductive Biology
Child and Adolescent Development
Mental Retardation
Fertility and Infertility

Inquiries about the program should be directed to:

Duane F. Alexander, M.D.
Deputy Director
National Institute of Child Health
and Human Development
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) - 496-1848

National Institute of Environmental Health Sciences

The award seeks to foster the development of clinical investigators in the field of environmental health/human toxicology and to support clinicians who work with research teams on problems arising from the exposures of human populations to environmental chemicals. (It is not meant to support the activities of "poison centers" and related researchers who deal with the effects of acute exposures to self-inflicted or accidentally inflicted toxic materials or clinical research on the toxicities of pharmaceuticals and other drugs.)

Inquiries about the program should be directed to:

Christopher O. Schonwalder, Ph.D.
Program Director
Research Manpower Development Section
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Telephone: (919) - 541-7634

National Heart, Lung, and Blood Institute

Cardiovascular, pulmonary, blood diseases and blood-banking sciences.

Inquiries about specific programs should be directed to:

Fann Harding, Ph.D.
Research Training and Development Officer
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) - 496-1817

Donald M. MacCanon, Ph.D.
Research Training and Development Officer
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A-08
Bethesda, Maryland 20205

Telephone: (301) - 496-1724

Sydney R. Parker, Ph.D.
Chief, Division of Prevention, Education, and Manpower
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A-12
Bethesda, Maryland 20205

Telephone: (301) - 496-7668

Letters of reference, inquiries regarding review procedures and two copies of the application should be directed to:

Executive Secretary
Research Manpower Review Committee
National Heart, Lung, and Blood Institute
Westwood Building - Room 550
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) - 496-7361

NOTICE

MODIFICATION OF CLINICAL INVESTIGATOR AWARD

K.W. 34; P.T. 1200180, 1200270

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES,
AND DIGESTIVE AND KIDNEY DISEASES

I. PURPOSE

The purpose of this notice is to announce the following changes in the terms of the Clinical Investigator Award (CIA) as offered by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

- A. A change in duration from three to five years.
- B. A change in the awardee's maximum base salary reimbursement from \$25,000 per year to \$40,000 per year, plus applicable fringe benefits.
- C. A change in the prohibition against serving as Principal Investigator on a research project grant while continuing to hold a CIA.

Details regarding these changes and a schedule for their implementation are given below.

II. BACKGROUND

The CIA is designed to support promising clinically-trained individuals as they develop into independent biomedical investigators. It enables candidates to investigate a well-defined problem under the sponsorship of one or more senior investigators and is intended to facilitate the transition from postdoctoral training to a career as an independent investigator. Eligibility is restricted to those holding health professional degrees in the clinical sciences (M.D., D.O., D.V.M., etc) who are citizens or permanent residents of the U.S. It is expected that candidates will have between four and seven years of postdoctoral experience including at least two years of clinical training and two years of research training. Holders of the Ph.D. award, with or without an accompanying health professional degree, are ordinarily not eligible. Such individuals might more appropriately consider applying for a Research Career Development Award. An investigator with appropriate seniority and background to supervise the development of the candidate must be identified as sponsor at the time of application. Provisions of the award require that the candidate spend at least 75% time on activities directly related to the objectives of the award. The candidate's base salary and applicable fringe benefits are available under the award as are funds of up to \$20,000 per year for research expenses.

III. MODIFICATIONS IN THE TERMS OF THE AWARD

- A. The duration of the NIADDK Clinical Investigator Award will be increased from three years to five years. Applications received for the October 1984 receipt date and thereafter should describe activities and request support for a five year period.
- B. The maximum base salary available under the award will be increased from \$25,000 per year to \$40,000 per year, plus applicable fringe benefits. The increased amount can be requested on competing and non-competing applications with requested start dates of October 1, 1984 or later. For non-competing awards, the higher salary and fringe benefits will be provided effective on the anniversary date of the award issued on or after October 1, 1984. Salary supplementation from non-Federal sources will be possible as it is currently.
- C. The terms of the original NIADDK Clinical Investigator Award specified that a recipient of that award could not also simultaneously serve as Principal Investigator on a research project grant or a New Investigator Research Award. That restriction is now lifted, and recipients of the CIA are encouraged to apply for and hold a regular research award or a New Investigator Research Award during the later years of the CIA. However, concurrent applications for a CIA and a regular research project award or New Investigator Research Award are not appropriate. No additional salary for the Principal Investigator may be drawn from a concurrently held research grant.

Further details concerning the NIADDK CIA may be obtained by contacting the following office:

Director
Division of Extramural Activities
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7793

NOTICE

TERMINATION OF SPECIAL EMPHASIS RESEARCH CAREER AWARDS: DIABETES
MELLITUS

P.T. 34; K. W. 1200350

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

NATIONAL INSTITUTE ON AGING

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Effective immediately, no applications for the Special Emphasis Research Career Award: Diabetes Mellitus (SERCA) will be accepted by these Institutes. This does not represent a decreased commitment of investigators in this important field, but rather the availability of other award mechanisms, both established and newly created, for this purpose.

Existing SERCAs are in no way affected by this announcement and will be funded through their expected termination dates.

Those applications for the SERCA which already have been received by the NIH Division of Research Grants to meet the annual receipt date of June 1, 1984, will be processed, reviewed for scientific merit, and a funding decision reached.

Future applicants are encouraged to apply for one of the several career development awards, both established and newly created, offered by these Institutes. Interested applicants should contact the appropriate Institute representative for more information:

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES

Lois F. Lipsett, Ph.D
Chief, Special Programs Branch,
Division of Diabetes, Endocrinology,
and Metabolic Diseases
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 603
Bethesda, Maryland 20205

Telephone: (301) 496-7433

NATIONAL INSTITUTE ON AGING

Evan C. Hadley, M.D.
Chief, Geriatrics Branch
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C-23
Bethesda, Maryland 20205

Telephone: (301) 496-1033

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Gilman Grave, M.D.
Chief, Nutrition and Endocrinology Section
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 7C-17
Bethesda, Maryland 20205

Telephone: (301) 496-5575

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Jerome G. Green, M.D.
Director, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 7A-17
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

INTEGRATED ACADEMIC INFORMATION MANAGEMENT SYSTEMS (IAIMS)

PLANNING, MODEL DEVELOPMENT, AND IMPLEMENTATION

P.T. 14; K.W. 1200700, 1004020, 0701025, 1004008

NATIONAL LIBRARY OF MEDICINE

Application Receipt Dates: November 1, March 1, July 1

I. PURPOSE

The National Library of Medicine (NLM) invites Resource Project Grant applications for planning and development projects leading to the implementation of Integrated Academic Information Management Systems (IAIMS) in medical centers and institutions with significant health sciences education, research, and/or patient care components.

The purpose of the IAIMS is to assist institutions in linking the library systems and the multitude of additional information systems that underpin the complex modern medical center into an integrated computer-based network.

Applications will be accepted on or before the standard NIH deadlines of November 1, March 1, and July 1 of each year. Institutional planning, development, and implementation of IAIMS prototypes represent a continuing priority interest of NLM. This initiative, however, does not preclude other Resource Grant applications that are not specifically related to this new NLM initiative, nor does it preclude grant applications in other NLM program areas (e.g., Research, Publication, or Career Development Awards) that may be conceptually related to IAIMS development.

II. BACKGROUND

Under the sponsorship of the NLM, the Association of American Medical Colleges undertook an analysis of trends in biomedical information transfer and their implications for health sciences libraries over the next decade (1). This report, as well as other publications (2-3), indicate that effective transfer and utilization of

This program is described in the Catalog of Federal Domestic Assistance, No. 13.879, Medical Library Assistance. Grants will be awarded under the authority of the Public Health Service Act, Section 395 (42 USC 280b-7) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 59a and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

recorded knowledge in the coming decades will require interactive network capabilities within medical centers. Such institutions now contain numerous information files. The efficiency and effectiveness of these files depend on a smooth, uninterrupted flow of accurate, daily operational information among functionally dependent areas, such as the laboratory, the nursing station, and the patient record. Optimal functioning of these institutions also depends on a smooth flow of accurate, relevant information generated by external sources; scientific publications and computerized databases are two such essential sources of new knowledge. While the biomedical community uses these kinds of information daily, ready access to this information through the many everyday operational information sources is rare. Information useful in decision making needs to be available at the time and place of demand and accessible in conjunction with other data.

III. OBJECTIVES

NLM support is available for: 1) institution-wide IAIMS planning and policy analysis; 2) IAIMS model development involving some segment or cross-section of the institution-wide strategic plan; and 3) implementation of detailed plans for a full-scale IAIMS prototype. These phases are sequential and are described as follows:

Planning Phase: Various models for strategic planning exist. Some functions to be considered in the particular planning model selected are: the preparation of an environmental forecast for the institution's next decade, the development of an institution information policy, the conduct of self-studies to assess the technological capabilities of the institution, and the assessment of the long- and short-range information management system needs and requirements in patient care, education, research, policy analysis, and administration. The development of scenarios as examples of IAIMS expected outcomes are very effective in illustrating the concept. Thus the resulting plan will assist in understanding what the IAIMS will accomplish, what the network architecture will be, who will execute the plan, and how the goals and objectives will be achieved.

Model Development Phase. Based upon the institution-wide IAIMS plan (described above), NLM assistance is available for testing IAIMS concepts on a small-scale basis in the environment involving information related to the research, education, and/or patient care mission of the institution. Any development model or test must relate to the IAIMS plan.

Implementation Phase: Those health science institutions which have completed an IAIMS plan and can demonstrate examples of successful modelling of critical elements of their plan may request NLM assistance to proceed with full-scale implementation.

IV. MECHANISM OF SUPPORT

IAIMS proposals will be funded under the Resource Project Grant Program. The IAIMS initiative is an ongoing and high priority NLM program. Depending on appropriations received and on commitments to other NLM grant programs, between \$500,000 and \$1,000,000 could be available in FY 1985 and 1986 for IAIMS

strategic planning, pilot development, and/or implementation. As has been the case since the inception of IAIMS, cost sharing continues to be significant in all projects.

Applicants for IAIMS Resource Project Grants may be hospitals and medical centers, academic health science centers, and colleges and universities with strong health sciences programs. For planning phase applications, the libraries must have online local access to their bibliographic records and other information delivery services or have made a commitment to implementing such a system within the planning period. For model development applications, a prerequisite is the existence of an IAIMS institutional plan including an information policy and an appropriate organizational structure. For implementation phase applications, an IAIMS institutional plan and evidence of successful outcomes of the modelling effort are prerequisites.

V. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this announcement will be evaluated for scientific and technical merit by the National Library of Medicine's initial review group, the Biomedical Library Review Committee (BLRC). The Board of Regents of the National Library of Medicine provides secondary review in terms of policy considerations and program goals. In the administration of awards, the policies and requirements of the grant programs of the Public Health Service (PHS) will apply.

Critical review elements will include:

- o Evidence of an appropriate institutional environment for successful IAIMS planning, development, or implementation. The demonstration of executive leadership and the involvement of faculty/staff in managing institutional information resources will be important review considerations.
- o The presence of well-developed computer and communications systems on which to establish expected or future IAIMS development. Such systems may include medical records, research databases, clinical data management, educational programs, biomedical communications, and health sciences library and learning resources.
- o The clarity and specificity of the IAIMS goals and objectives, including projected tasks, the expected outcomes, and the attendant risks. Scenarios depicting the anticipated outcomes in the planning, development, and implementation phases are strongly encouraged. A design for assessing the project and its attainments is an essential component. The project plan shall conform to the requirements of the application instructions.
- o The institutional commitment of appropriate technical and program personnel and evidence of successful introduction of new technologies. Previous work and preliminary studies pertinent to the proposal should be cited. Proposed projects must include a clear and substantial role for the health sciences library.

- o The identification and commitment of institutional resources to support and further develop IAIMS. The NLM Resource Grant Program provides initial investment, seed money, or start-up costs. The rules and regulations governing the program require assurance of "adequate and continuing financial support of the applicant's proposed activity from other non-Federal sources during and after the period of the award."

VI. METHOD OF APPLYING

Application forms, instructions, and additional information may be obtained from:

Biomedical Information Support Branch
Extramural Programs
National Library of Medicine
Bethesda, Maryland 20209

Telephone: 301-496-4221

Applicants should clearly identify the application as a response to this announcement by entering the title **"IAIMS PLANNING—NLM RESOURCE GRANT PROGRAM"** or **"IAIMS MODEL DEVELOPMENT—NLM RESOURCE GRANT PROGRAM"** or **"IAIMS IMPLEMENTATION—NLM RESOURCE GRANT PROGRAM"** as appropriate.

The total project period may not exceed 3 years. Indirect costs are not applicable.

Applications must be received by the standard NIH deadlines, i.e., November 1, March 1, and July 1. Late submissions will be held over for the subsequent review cycle.

VII. REFERENCES

1. Matheson, Nina, and John A.D. Cooper. "Academic Information in the Academic Health Sciences Center: Roles for the Library in Information Management," *Journal of Medical Education*, Vol. 57 (10), October 1982, Part 2.
2. Piemme, Thomas E. and Marion J. Ball. *Executive Management of Computer Resources in the Academic Health Center; A Staff Report*. Washington, Association of Academic Health Centers, January 1984. 34 pp.
3. Wilson, Marjorie, et al. *The Management of Information in Academic Medicine; An Assessment of the Application of Technology, Policy Consequences, and Needed Changes in the Present System*. Washington, Association of American Medical Colleges, 1982. 2 volumes.

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 1200170, 1200180, 0404000

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral and health sciences.

Programs Available to U.S. Citizens or Permanent U.S. Residents:

ACADEMY OF FINLAND POSTDOCTORAL RESEARCH FELLOWSHIPS

ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH FELLOWSHIPS

FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH POSTDOCTORAL FELLOWSHIPS

NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE PROGRAM

IRISH MEDICAL RESEARCH COUNCIL POSTDOCTORAL FELLOWSHIP

ISRAELI MINISTRY OF HEALTH POSTDOCTORAL RESEARCH FELLOWSHIPS

NORWEGIAN RESEARCH COUNCIL FOR SCIENCE AND THE HUMANITIES POSTDOCTORAL FELLOWSHIPS

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS

VISITING SCIENTISTS PROGRAM OF THE NATIONAL SCIENCE COUNCIL, TAIWAN

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical or health sciences and some postdoctoral experience.

The receipt date for all applications except those to the Alexander von Humboldt Foundation and the Visiting Scientists Program for the National Science Council, Taiwan is October 1, 1984. Applications for the Alexander von Humboldt Foundation Postdoctoral Research Fellowships and the Visiting Scientists Program for the National Science Council, Taiwan are available and are accepted throughout the year. For those fellowship programs with an October 1 receipt date, application kits will be available from April 1, 1984 to September 15, 1984. The organization that provides financial support for each of the programs selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

All correspondence should refer clearly to the specific program of interest. For further information, please send a self-addressed label with your request to:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENTCHARACTERIZATION OF MULTI-DRUG RESISTANT HUMAN AND OTHER MAMMALIAN TUMOR CELL LINES

P.T. 34; K.W. 0701038, 1200250, 1200260, 1002004

DIVISION OF CANCER TREATMENT

NATIONAL CANCER INSTITUTE

Application Receipt Dates: November 1, March 1, July 1

The National Cancer Institute (NCI) is seeking grant applications for support of research projects to identify and characterize multi-drug resistant tumor cells. The development of drug resistance in tumor cell populations treated with chemotherapeutic agents has been recognized as a major problem in cancer treatment. The Division of Cancer Treatment (DCT) desires to support research in this area in order to increase understanding of drug resistance phenomena and develop therapeutic strategies to overcome or circumvent the problem.

This announcement is specifically targeted to stimulate research in the area of multi-drug resistance, also referred to as pleiotropic drug resistance (PDR). Detailed studies in Chinese hamster and murine cell systems have shown that under some selective conditions, e.g. Colchicine, Vincristine, or Adriamycin treatment, cell populations demonstrating a multi-drug resistant (PDR) phenotype emerge. In many of these cells, broad spectrum resistance to multiple agents of different modes of action is associated with reduced intracellular accumulation of drug and the appearance of a membrane glycoprotein marker. Recently, laboratory evidence has been presented that multi-drug resistant cells also occur in human tumor cell populations. This latter evidence is consistent with clinical experience, particularly with previously treated patients, wherein resistance to multiple agents of different modes of action is observed.

While some potentially important collateral sensitivities to established antitumor drugs have been observed among mammalian cell types showing the multi-drug resistant phenotype, it seems likely that new agents specifically useful in treating these resistant cells will be needed. Development of such agents will require additional insight into the mechanism(s) of PDR and an adequate number of well characterized multi-drug resistant cell lines in which new agents can be studied. This announcement is intended to stimulate applications for grants which propose to develop and characterize multi-drug

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

resistant human or mammalian tumor cell lines which have potential for this purpose. The primary emphasis in applications submitted in response to this program announcement should be on elucidating the mechanism of resistance in multi-drug resistant cell populations.

Multi-drug resistant cells may be selected in vitro or derived directly from patients or animals bearing tumors which have been shown to be resistant to chemotherapy. While the specific approaches and methods for development and characterization of the resistant cells will be left to the applicant, it is suggested that the following areas be addressed in the application.

- A. Mechanism(s) of multi-drug resistance
- B. Stability of the drug resistant phenotype
- C. Extent of cross resistance
- D. Tumorigenicity of the drug resistant cells
- E. Verification of the origin of the cells

Applications in response to this announcement will be reviewed in accordance with the usual National Institutes of Health (NIH) peer review procedures. They will first be reviewed for scientific and technical merit by a review group (Study Section) composed mostly of non-government scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board. The review criteria customarily employed by the NIH for regular research grant applications will be utilized. All Public Health Service (PHS) grants policies, including cost sharing, apply to applications received in response to this program announcement.

I. DEADLINE

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates are November 1, March 1 and July 1.

II. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the grants and contracts business office at most academic and research institutions or from the Division of Research Grants (DRG), NIH. In space #2 on the first page of this form, indicate the title of this program announcement. Additionally, a brief covering letter should accompany the application indicating that it is being submitted in response to this program announcement. The original and six copies of the application should be submitted to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, contact:

Dr. Robert H. Shoemaker
Acting Head, Cell Culture Section
Drug Evaluation Branch
Developmental Therapeutics Program
Division of Cancer Treatment
National Cancer Institute
Blair Building - Room 419
Bethesda, Maryland 20205

Telephone: (301) 427-8700

ANNOUNCEMENT

AUTISM AND RELATED BEHAVIORAL DISORDERS

P.T. 34; K.W. 0701007, 0701029, 1002019, 1002030, 1200890, 1201160, 0404000, 1200430, 1200900, 1200220, 1200280

NATIONAL INSTITUTE OF MENTAL HEALTH

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the National Institute of Mental Health (NIMH) jointly request the submission of research grant applications on autism and related behavioral disorders. Both NINCDS and NIMH are interested in research on neurobiological and genetic factors in autism and related behavioral disorders. In addition, NIMH encourages studies of relevant environmental factors and treatments. Applications will be assigned to the appropriate Institute(s) for funding consideration based on Public Health Service (PHS) referral guidelines.

I. BACKGROUND

Autism affects about 5 out of 10,000 children; related behavioral disorders affect an additional 10 out of 10,000 children. Autism and related behavioral disorders have come to be regarded as complicated central nervous system disorders involving communication (including language), motility patterns, attention, responses to environmental stimuli, and (most specifically) social interactions. These disorders seem to have their origin before, at, or shortly after birth.

A consensus among investigators as to the general neurobiologic nature of the defects underlying autism and related behavioral disorders leads to the need for research on the specific localization of the various dysfunctions implicated in autism, characterization of the dysfunctions, and causation of these severely handicapping conditions. Recent clinical studies of autism have suggested that brain lesions may be concentrated in deep subcortical regions (mesalimbic and basal ganglia). Epidemiologic evidence suggests that causations may be multiple, ranging from association with viral encephalitides to genetic predisposition, and may produce deficiencies in a number of cognitive, linguistic, affective, and social domains that are broader than autism per se. A major issue is whether communication or social defects are more central to the brain dysfunction of autistic and similar persons.

These programs are described in the Catalog of Federal Domestic Assistance Nos. 13.853, Stroke, Nervous System Trauma and 13.242, Mental Health Research Grants. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. These programs are not subject to Health Systems Agency review.

Of interest to both NINCDS and NIMH are studies to define neuropsychological, neurophysiological, and neuropathological mechanisms, and neuropharmacological interventions associated with clinically and behaviorally well-characterized autism or disorders related to autism. Studies involving animals are also encouraged; including experiments which would include collaboration among physiological psychologists, behavioral veterinarians, and clinician-investigators familiar with human behavioral disorders including autism. In addition, NIMH encourages research grant applications to develop and assess behavioral, psychosocial, or somatic treatments for these disorders. The NIMH request is for research on highly specified treatment regimens and does not include the evaluation of the delivery of services.

II. RESEARCH GOALS

Delineation of neuropsychological deficits underlying the cognitive, affective, social, and communicative impairments of autistic persons should be focal points of human studies, both to facilitate comparison with animal models and to suggest localization of brain lesions. Genetic studies should also include detailed neuropsychological profiles of subjects and family members.

Of particular importance are studies using electrophysiological, biochemical, and imaging techniques which can contribute to differential localization of lesions with the brains of autistic compared to nonautistic (but otherwise neurodysfunctional populations). Research must progress beyond the ability to differentiate the normal from the abnormal. It must seek neuropsychological, neurophysiological, neurochemical, and behavioral markers necessary to differentiate autism from other functional disorders. Biochemical studies uncovering neurotransmitter/receptor/mechanisms in these same populations are also encouraged. Where neuropathological data can be obtained from autistic and other dysfunctional populations known to be affected by the same disease (e.g., congenital rubella, tuberous sclerosis), research should focus on the differential localization associated with autistic/nonautistic clinical pictures. Such neuropathological studies might include the post-mortem study of the cytoarchitectonic characteristics of the brains of autistics as compared to other developmentally disabled persons (e.g., language-disabled, dyslexic, etc.). Research should be directed toward the correlation of behaviors with brain mechanisms and the identification of risk factors for autism leading to studies of preventive interventions.

Longitudinal studies have shown that autistic children do not outgrow their disorder but, in most cases, remain impaired. There is a critical need for research to develop and evaluate new treatments or combinations of treatments. Both NINCDS and NIMH are interested in neuropharmacology; NIMH emphasis is on producing cognitive, affective and social improvements that generalize beyond the experimental situation, while NINCDS emphasizes studies revealing brain changes during and after intervention.

In addition to the above, NINCDS and NIMH encourage research on treatment of childhood autism which could lead to development of new therapies or treatment approaches, including studies of interactive, additive, or inhibitory effects of combined treatments; formulation and testing of hypotheses, experimental designs, and clinical or animal models of treatments; clinical trials to evaluate efficacy of single or multimodality treatments; studies on the adverse effects of special

treatment regimens; development of treatment assessment research strategies and methodologies; studies of treatment processes, including the role of nonspecific factors in treatment response such as patient/therapist interactions.

III. ELIGIBILITY

Private, nonprofit or for-profit and public institutions (such as units of State or local government and authorized units of the Federal Government) are eligible to apply for grants under this announcement.

IV. TERMS AND CONDITIONS OF SUPPORT

Support for applications submitted in response to this announcement will be through grants for individual research projects or for program projects. (Applicants for program projects should consult in advance with NIH staff.)

Applications will be assigned for funding consideration on the basis of the focus of the research and PHS referral guidelines. Generally, only one Institute will provide funding but it is possible, particularly for large projects, that the other may contribute toward funding a project.

Grant funds may be used only for those expenses clearly related to and necessary to carry out research projects, and must be expended in conformance with the Public Health Service Grants Policy Statement.

In general, grant funds may be used for: (1) direct costs which are necessary to carry out the project, including salaries, consultant fees, supplies and equipment, and essential travel; (2) actual indirect costs to cover related overhead.

V. METHOD OF APPLYING

State and local government agencies should use form PHS-5161. All other applicants should use the standard PHS-398 (revised 5/82) research grant application form. **"Autism and Related Behavioral Disorder"** should be typed in item #2 on the face page of the application.

Application kits including instructions may be obtained from most institutional business offices or from offices of sponsored research for most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following offices may be contacted for the necessary application material:

Office of Grants Inquiries
Division of Research Grants
Westwood Building
5333 Westbard Avenue
National Institutes of Health
Bethesda, Maryland 20205

Grants Operations Section
National Institute of Mental Health
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

The original and 6 copies (2 copies if PHS-5161 is used) of the application must be sent directly to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

VI. REVIEW PROCEDURES AND CRITERIA

Review Procedures

Applications will be reviewed for scientific merit and relevance to program goals in accordance with the standard review procedures of the Public Health Service; that is, each application will be assessed first for scientific merit review by an appropriate Initial Review Group (IRG) of non-Government scientists and then for policy and program relevance by the appropriate National Advisory Council.

Review Criteria

- relevance of the application to the objectives, goals and scope of the announcement
- the significance of the proposed research
- the scientific and technical merit of the research protocol(s)
- expertise, qualifications, and commitment of the proposed personnel and their ability to devote adequate time and effort to the proposed research
- appropriateness of the resources and the environment
- a realistic plan and timetable for completing the research
- appropriateness of the budget for the proposed research
- adequacy of proposed procedures for protecting human subjects.

Applications in response to this announcement will be reviewed according to the usual schedule:

<u>Receipt of Applications*</u>	<u>Initial Review</u>	<u>Advisory Council Review</u>	<u>Earliest Starting Date</u>
Oct 1/Nov 1	February	May	July 1
Feb 1/Mar 1	June	September-October	December 1
June 1/July 1	October	January-February	April 1

VII. STAFF CONSULTATION

Potential applicants are encouraged to contact Institute staff. It is suggested that this be done in writing by submitting a one- or two-page description of the research planned to the addresses below.

Studies of the neurobiologic nature, description, characterization, diagnostic classification, etiology, natural history and/or prevention of autism and related behavior disorders:

NINCDS Martha Bridge Denckla, M.D.
 Chief, Autism and Behavioral Disorders Section
 Developmental Neurology Branch
 National Institute of Neurological and Communicative
 Disorders and Stroke
 Bethesda, Maryland 20205

NIMH Sigmund Dragastin, Ph.D.
 Assistant Chief, Center for Studies of Child
 and Adolescent Psychopathology
 Clinical Research Branch
 Parklawn Building - Room 10C-24
 National Institute of Mental Health
 5600 Fishers Lane
 Rockville, Maryland 20857

Studies of the development, mechanisms and processes, methodology of evaluation, and clinical assessment of pharmacologic therapy and other types of somatic treatment:

NINCDS Martha Bridge Denckla, M.D.
 Chief, Autism and Behavioral
 Disorders Section
 Developmental Neurology Branch
 National Institute of Neurological and
 Communicative Disorders and Stroke
 Bethesda, Maryland 20205

NIMH Natalie Reatig
 Program Specialist, Pharmacologic and
 Somatic Treatments Research Branch
 Parklawn Building - Room 10C-06
 National Institute of Mental Health
 5600 Fishers Lane
 Rockville, Maryland 20857

* The first date in each cycle is for program project applications; the second date is for the new regular research grant applications.

Studies of the efficacy, safety, efficiency, mechanisms and process of psychosocial treatment:

NIMH

Barry E. Wolfe, Ph.D.
Assistant Chief
Psychosocial Treatments Research Branch
Parklawn Building - Room 10C-05
National Institute of Mental Health
5600 Fishers Lane
Rockville, Maryland 20857

Studies aimed at improving communication and speech and language skills:

NINCDS

Christy L. Ludlow, Ph.D.
Health Scientist Administrator
Communicative Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
Bethesda, Maryland 20205

ANNOUNCEMENT

LIFE SCIENCES INVESTIGATIONS IN SPACE: Announcement of Opportunity

NASA AO NO. OSSA-2-84

P.T. 34; K.W. 1200180, 1015000, 0701044, 1200240, 1200840, 1200780, 1200270, 0608007, 0202022

LIFE SCIENCES FLIGHT EXPERIMENTS PROGRAM

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

I. BACKGROUND

On May 15, 1984, the National Aeronautics and Space Administration (NASA) issued an Announcement of Opportunity (AO No. OSSA-284) which invited scientists to propose life sciences studies which could be carried out on the Space Shuttle/Spacelab system between 1986 and 1991. The proposed investigations which may be self-contained or may involve procedures or measurements carried out by the Shuttle/Spacelab crew, should consist of distinct and innovative approaches for addressing one or both of the objectives described in Section II below.

The AO No. OSSA-2-84 describes the space flight opportunities, the broad life sciences objectives which NASA seeks to support during this period, and the specific instructions and regulations governing the submittal, evaluation, and selection of life sciences flight investigations for support by NASA. NASA is particularly interested in those investigations which are related to ensuring that a permanent human presence in space can be realized and sustained.

Investigations selected as a result of AO No. OSSA-2-84 will normally be accommodated on Shuttle flights of the Spacelab pressurized module, but other modes of accommodation are possible and will be used if appropriate. The Spacelab pressurized module is a laboratory facility which is capable of supporting complex, interdisciplinary life sciences research in space. In general, the Space Shuttle/Spacelab remains in orbit for approximately 7 to 10 days. The crew for Spacelab missions can consist of highly trained research scientists as well as career astronauts. NASA has developed and will maintain a number of special facilities and an inventory of standard and specialized life sciences laboratory equipment to facilitate research in space.

II. RESEARCH OBJECTIVES

Proposals submitted in response to AO No. OSSA-2-84 must address scientific questions related to one or both of the following objectives and must clearly require space flight for their accomplishment.

A. Biomedical Research

This objective is to investigate those areas of biomedical research which are concerned with the safety, well-being, comfort, and productivity of humans during space flight. The scope of the research proposed to address this objective can include, but is not limited to investigations in one or more of the following scientific areas: neurovestibular function, cardiovascular and pulmonary function, musculoskeletal function, metabolism and nutrition, human capability and performance, clinical medicine, and countermeasures.

B. Biological Research

This objective is to investigate fundamental questions in biology and relates to NASA's interest in those investigations which aim to develop an understanding of the role gravity plays in the form and function of organisms on Earth.

III. PROPOSAL SUBMISSION INFORMATION

The information contained in this Announcement is not sufficient to prepare a proposal in response to AO No. OSSA-2-84. Proposals submitted in response to AO No. OSSA-2-84 must be prepared and submitted in accordance with the instructions contained in the document entitled "**Announcement of Opportunity, Life Sciences Investigations in Space 1986-1991; AO No. OSSA-2-84**" issued by the National Aeronautics and Space Administration, Washington, D.C., May 15, 1984. Persons interested in receiving a copy of this Announcement of Opportunity should address a written request to:

Chief, Flight Programs Branch
Life Sciences Division
NASA Headquarters (EBF)
Washington, D.C. 20546

By making such a request, the individual's name will be added to NASA's Life Sciences mailing list.

IV. PROPOSAL SCHEDULE

This NASA Announcement of Opportunity will be in effect through 1987. Proposals may be submitted to NASA at any time; however, a Notice of Intent to Propose is required prior to the submission of a proposal. The following schedule is planned for the acquisition of investigations under this Announcement.

	<u>First Period</u>	<u>Second Period</u>	<u>Third Period</u>
Notice of Intent to Propose Due	Aug. 1, 1984	Feb. 1, 1986	Aug. 1, 1987
Proposal Due Dates	Oct. 1, 1984	Apr. 1, 1986	Oct. 1, 1987
Selection Announcement	Nov. 1985	May 1987	November 1988



V. ACKNOWLEDGEMENT

This announcement has been inserted in the NIH Guide for Grants and Contracts through the courtesy of the Guide publications staff. The Life Sciences Division at NASA is grateful for the opportunity of having this information distributed to the broad community currently receiving this Guide.

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 9, August 3, 1984

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National Institutes of Health

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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PREAMBLE

PROPOSED U.S. GOVERNMENT PRINCIPLES
FOR THE UTILIZATION AND CARE OF VERTEBRATE
ANIMALS USED IN TESTING, RESEARCH, AND TRAINING

P.T. 34; K.W. 0201011, 1014002

In the April 5, 1984, Special Edition of the NIH Guide for Grants and Contracts (Vol. 13, No. 5), the Public Health Service (PHS) published a proposed amendment to the PHS Extramural Animal Welfare Policy as originally specified in DHEW Grants Administration Manual Chapter 1-43, "Animal Welfare."

The proposed policy, entitled "Proposed PHS Policy on Humane Care and Use of Animals by Awardee Institutions," was published in order to provide interested parties and individuals an opportunity to comment on the proposed changes.

The current PHS Extramural Animal Welfare Policy contains twelve "Principles for Use of Animals," which were published in the proposed policy (article III) essentially as they appear in the current policy. The current principles also appear as an appendix to the NIH Guide for the Care and Use of Laboratory Animals under the heading "Guidelines for the Use of Experimental Animals."

The preamble to the proposed PHS policy stated that "The Principles remain virtually unchanged in the proposed policy because the PHS is discussing with other Federal agencies the possibility of developing governmentwide principles for the care and use of laboratory animals. In the event that such principles are developed, they may be inserted in the policy at a later date."

The Interagency Animal Research Committee (IRAC), comprised of representatives from Federal agencies that conduct, support or regulate the use of animals for testing, research and training, has developed proposed "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training." The proposed principles are published below.

Public comment on the proposed U.S. Principles is invited, and will be made available to the IRAC for consideration in the development of a final version of the principles. The PHS is considering the inclusion of the final version of the principles in the PHS Policy, which, as proposed, states that all PHS grantee institutions must accept the principles as "mandatory." The PHS would not, however, include the waiver provision that accompanies the IRAC principles and on the basis of public comments may make other modifications in the principles prior to including them in the PHS Policy.

The PHS scheduled three open hearings on the proposed PHS Policy: July 19 in Kansas City, July 24 in Boston, and August 2 in Seattle.

Comments on the proposed U.S. Principles must be received on or before September 21, 1984, if they are to be given full consideration. Please send comments to the following:

Ms. Carol Young
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31 - Room 4B09
Bethesda, Maryland 20205

INTERAGENCY RESEARCH ANIMAL COMMITTEE PROPOSED

U.S. GOVERNMENT PRINCIPLES FOR THE UTILIZATION AND CARE OF
VERTEBRATE ANIMALS USED IN TESTING, RESEARCH, AND TRAINING

The development of knowledge necessary for the improvement of the health and well-being both of man and of animals requires recourse to in vivo experimentation with a wide variety of animal species. Methods such as mathematical models, computer simulation and in vitro biological systems should be used wherever appropriate. Whenever U.S. Government Agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals shall be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal, state and local laws and prescribed policies.¹
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of biological knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality, and the minimum number required to obtain scientifically valid results.
- IV. Proper care of animals, including the avoidance or minimization of discomfort, distress or pain is a moral imperative. Lacking evidence to the contrary, investigators should consider that procedures that cause pain in human beings cause pain in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

¹ For guidance throughout these Principles the reader is referred to the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the experiment or, if appropriate, during the experiment.
- VII. The living conditions of animals kept for biomedical purposes should contribute to their health and comfort. Normally, the housing, care, and feeding of all animals used for these purposes must be supervised by a properly qualified veterinarian. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

If it is deemed necessary to waive one of the foregoing principles, the decision should be made, with due regard to the provisions of Principle II, by an appropriate review group, such as an institutional animal research committee. Such waivers should not be made where the primary purpose is teaching or demonstration.

NOTICE
CHANGE IN RECEIPT DATE

INTRAUTERINE GROWTH RETARDATION

RFA: 84-HD-05

P.T. 34; K.W. 1201040, 1201070, 1200370, 1201270, 1002019, 0607024, 0701005

PERINATAL EMPHASIS RESEARCH CENTER

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

A Notice of availability for the above-named Request for Applications (RFA) appeared in the NIH Guide for Grants and Contracts, Vol. 13, No. 8, June 29, 1984. The deadline for receipt of applications has been changed from October 1, 1984 to December 1, 1984. Prospective applicants should note that the National Institute of Child Health and Human Development (NICHD) requests a letter of intent by September 1, 1984.

A complete Request for Applications entitled "**Intrauterine Growth Retardation**" and guidelines concerning "NICHD Research Center Programs" may be obtained from:

Dr. Charlotte Catz
Head
Pregnancy and Perinatology Section
Clinical Nutrition and Early Development Branch
Center for Research for Mothers and Children
National Institute of Child Health and
Human Development
Landow Building - Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-5575

NOTICE

CONSTRUCTION GRANT APPLICATIONS

P.T. 02; K.W. 1201200

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) announces that effective on the receipt date February 1, 1985, all construction grants will have an annual receipt date of February 1. Funding based on that receipt date will be made available during the following fiscal year.

NOTICENIH/FDA REGIONAL WORKSHOPS-PROTECTION OF HUMAN SUBJECTS

P.T. 34; K.W. 0701028, 1014002

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institution officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. The current schedule includes:

<u>DATE</u>	<u>LOCATION</u>	<u>CONTACT</u>
September 13-14, 1984	Stanford, CA	Ms. Phyllis S. Hall Human Subjects Coordinator Stanford University Encina Hall Stanford, CA 94305 Telephone: (415) 497-3638
October 22-23, 1984	Washington, DC	Mrs. Lucille Holland Office of the Institutional Review Board Room 214, Annex 2 Freedman's Square Howard University Washington, D.C. 20059 Telephone: (202) 636-7812
January, 1985	Los Angeles/Southern California	

A final list of dates and locations will be published at a later date. For specific program and registration information, contact:

Roberta H. Garfinkle
Office for Protection from
Research Risks
National Institutes of Health
Building 31 - Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CNURU-01

CORE GRANTS FOR CLINICAL NUTRITION RESEARCH UNITS

P.T. 34, 04; K.W. 0202022, 1200180, 0701042, 0502000

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND
KIDNEY DISEASES

NATIONAL INSTITUTE ON AGING

Application Receipt Date: October 15, 1984

I. BACKGROUND

The National Institutes of Health (NIH) invites applications for core grants in support of Clinical Nutrition Research Units (CNRUs). A CNRU is an integrated array of research, educational, and service activities that is oriented toward human nutrition in health and disease. Core grants facilitate the planning and coordination of the activities of the Units primarily by providing funding for facilities and associated staff that serve the various projects of the Unit on a shared basis. This solicitation is a joint effort of the following three Institutes of the NIH: 1) National Cancer Institute (NCI), 2) National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDDK), and 3) National Institute on Aging (NIA).

The NIH has traditionally sponsored the component activities of CNRUs through a variety of award mechanisms; the principal ones have been research project grants and support for research training. A 1979 initiative, core grants for shared nutrition research (CNRU) facilities have become an invaluable addition, especially in promoting multidisciplinary interactions. This approach has ensured that a CNRU has multiple sponsors, both Federal and non-Federal, and thereby reduces the likelihood that it will become unduly dependent upon any one source of funds for its continuing operations. Funding for educational programs and nutritional support services (patient care) have generally been sought from sources other than the NIH.

The NIH will continue to provide support for certain activities to be carried out by CNRUs through the customary research project grant, and management of CNRU grants and other assistance mechanisms will be governed by the laws, regulations, and policies and other requirements which prevail for research grants.

II. OBJECTIVES OF THIS SOLICITATION FOR CORE GRANT APPLICATIONS

As a means of encouraging the desired multidisciplinary approach to clinical nutrition research, the NIH seeks to foster the development and operation of CNRUs. This solicitation for core grant applications is designed to complement NIH-supported project grants and training awards and relevant activities funded from other sources. The specific objectives are:

- A. To create or strengthen foci in biomedical research institutions for multidisciplinary research in clinical nutrition in order to develop new knowledge about specific nutrients in health throughout the life cycle, and in the prevention and treatment of disease.
- B. To strengthen training environments in order to improve the education of medical students, house staff, practicing physicians, and allied health personnel in clinical nutrition.
- C. To enhance patient care and promote good health by focusing attention on clinical nutrition and generating nutritional information for the public.

III. ESSENTIAL COMPONENTS OF A CNRU

A CNRU, at a minimum, must comprise the following seven components:

1. Research with human subjects and populations.
2. Laboratory investigations.
3. Research training.
4. Shared facilities and research services.
5. Education programs for medical students, house staff, practicing physicians, and allied health personnel.
6. Research components of nutritional support services.
7. Public information activities.

A CNRU is most readily developed in a medical school, a school of public health, or a research hospital, but is not limited to these settings. Eligibility is limited to domestic institutions.

IV. FUNDING

It is envisioned that core grants to CNRUs generally will be supported by a single NIH Institute with the selection by Institutes to be based on the dominant thrust of the application. Mechanisms for joint funding by two or more Institutes are available if considered necessary or appropriate. However, each Institute participating in this announcement will support basic nutrition research and nutrition research outside of its area of emphasis, provided the latter is not the dominant thrust of the application. The NIH plans to make approximately three new core grants in FY 1985. Although this program is included and provided for in the financial plans for FY 1985, award of grants in that fiscal year is contingent upon ultimate allocation of appropriated funds for this purpose.

V. METHOD OF APPLYING

Prospective applicants are asked to contact program staff by telephone or to submit a one page letter of intent. This telephone contact or letter of intent should be addressed to the contact persons listed below at the address indicated. The Institutes request such contact in order to provide an indication of the numbers of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted, nor is it a mandatory requirement for the submission of the application.

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions, or which may be obtained directly from the NIH Division of Research Grants. The phrase **"NIH CLINICAL NUTRITION RESEARCH UNIT (CNRU) CORE AWARDS RFA"** should be typed in box 2 of the first page of the application.

The CNRU awards are expected to be made during FY 1985. Applications for this competition should be received **NO LATER THAN** October 15, 1984. This announcement is for a single receipt date.

VI. COPIES OF THE RFA MAY BE OBTAINED FROM:

Van S. Hubbard, M.D., Ph.D.
Director, Nutrition Program
National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases
Westwood Building - Room 3A18B
Bethesda, Maryland 20205

Telephone: (301) 496-7823

Evan Hadley, M.D.
Chief, Geriatrics Branch,
National Institute on Aging
Building 31 - Room 5C21,
Bethesda, Maryland 20205

Telephone: (301) 496-1033

Ritva R. Butrum, Ph.D.
Diet and Cancer Branch
Prevention Program
National Cancer Institute
Blair Building - Room 619
Bethesda, Maryland 20205

Telephone: (301) 427-8753

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATION: RFA84-AG-03ALZHEIMER DISEASE RESEARCH CENTERS

P.T. 34; K.W. 1201230, 1200180, 0404000, 1200270

NATIONAL INSTITUTE ON AGING

Application Receipt Date: November 9, 1984
Letter of Intent Receipt Date: October 1, 1984

I. BACKGROUND

The National Institute on Aging (NIA) is inviting grant applications from interested institutions to establish centers of excellence devoted to the study of Alzheimer disease and related disorders. This type of solicitation (the RFA) is issued to encourage coordinated multidisciplinary research in an area of special importance to the NIA, the National Institute of Mental Health (NIMH), the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the National Institute of Allergy and Infectious Diseases (NIAID). The general purpose of the Alzheimer Disease Research Center (ADRC) is to support new research and to enhance ongoing research by providing core support to bring together biomedical, behavioral, and clinical science investigators in a manner that will enrich the effectiveness of Alzheimer disease research and ultimately improve health care delivery. An ADRC will be expected to foster three related functions: conducting multidisciplinary research; training scientists and clinicians and teaching and/or transferring new information concerning Alzheimer disease and related disorders.

II. ELIGIBILITY

To be eligible for a center grant under this program, the potential applicant institution must have ongoing, independently supported research and must propose new research in the area of Alzheimer disease and related dementing disorders of the aged. Relevant research projects supported by a Department of Health and Human Services (DHHS) agency, the VA or a foundation can become affiliated with a Center.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional NIH grant-in-aid. Although this program is provided for in the financial plans of the NIA, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose. The intent is to fund up to five ADRC grants. This specific amount will depend on the merit and scope of the applications received. These applications are not expected to compete for funding within the general pool of dollars available for other investigator-initiated research proposals. Only applications of sufficiently high scientific merit will be funded.

IV. REVIEW PROCEDURES AND CRITERIA

All applications responding to the RFA will be reviewed for scientific and technical merit by an initial review group which will be convened solely to review these applications. Although a site visit may be made, each proposal should be complete in itself, and should be prepared as if no visit is expected. The factors to be considered in the evaluation of the scientific merit of each application will be those used in the review of traditional research-project grant applications.

V. METHOD OF APPLYING

The application must be submitted on form PHS 398, the application form for the traditional research-project grant. Supplemental instructions for preparing ADRC proposals are available from the program administrator at the address below. To identify these applications as being in response to the RFA, check "yes" on item 2 of page 1 of the application and enter the title: **"ALZHEIMER DISEASE RESEARCH CENTERS"** and the RFA number 84-AG-03. Guidelines for ADRC Applications are available from NIA. See Section on "Inquiries."

Although not a prerequisite for applying, potential applicants are encouraged to submit to the program administrator indicated below a non-binding letter of intent to apply, post-marked no later than October 1, 1984. The letter of intent is not mandatory and does not influence review or funding decisions, but it will enable the NIA to plan the review, and will ensure that each potential applicant receives relevant program information prior to expending considerable effort in application preparation.

The deadline for receipt of applications by the NIH Division of Research Grants (DRG) is November 9, 1984. Send the original and five copies to DRG, and simultaneously submit a single copy to Chief, SRO/OPEA/NIA, Building 31, Room 5C12, Bethesda, MD 20205.

Inquiries regarding this announcement or copies of more detailed RFA and guidelines which outline the ADRC requirements and the method of applying may be directed to the program administrator:

Zaven S. Khachaturian, Ph.D.
Chief, Physiology of Aging Branch
Biomedical Research and Clinical Medicine Program
National Institute on Aging
National Institutes of Health
Building 31C - Room 5C-27
Bethesda, Maryland 20205

Telephone: (301) 496-9350

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-AM-04

DIGESTIVE DISEASES CORE CENTERS

P.T. 34, 04; K.W. 1200400, 1200180, 1200370, 1200770, 0701042, 1200460

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Date: November 16, 1984

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) invites applications for Digestive Diseases Core Centers (DDCC) to be initiated in Fiscal Year 1985. The centers component of the Digestive Diseases Program of the NIADDK is being expanded at the recommendation of the National Digestive Diseases Advisory Board and Institute staff. This is the second announcement in the request for DDCC. The first announcement and funding of Centers was in Fiscal Year 1984.

The objectives of the Core Center are to bring together, on a cooperative basis, clinical and basic science investigators in a manner which will enhance and extend the effectiveness of research being conducted in the field of digestive diseases. Within the research activities of the Center should be research that is relevant to the underlying cause, mechanism, diagnosis, early detection, prevention, control and treatment of digestive diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases. The focus can be a disease such as pancreatitis, functional bowel disease, inflammatory bowel disease, chronic hepatitis; an organ such as liver, esophagus, large bowel; a process such as absorption, secretion, motility or an appropriate combination thereof which may also include areas of relevant technology.

The Core Center grant is a mechanism designed to enhance and extend the effectiveness of a group of related projects and investigators that are already funded through other mechanisms such as Research Project Grants or Research Program Projects. In this

This program is described in the Catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

respect the Core Center mechanism builds upon an established base of research excellence. The Core Center grant may provide funds for (1) core resources such as tissue culture, immunoassay or biostatistics units which must be utilized by at least two or more center participants; (2) pilot/feasibility projects to encourage new investigators or investigators from other fields to pursue new and innovative ideas to a point where they can compete for independent support; and (3) program enrichment funds to provide for small conferences or symposia, advisory board expenses and special consultants. In addition, temporary salary support for one named new investigator in a specified area of research and with a defined pilot/feasibility project may be requested for up to 24 months, with subsequent individuals to be named and reviewed by the Center's Advisory Board and the NIADDK.

Institutions that have the necessary foundation of multidisciplinary digestive diseases-related research are encouraged to apply for the DDCC. At least fifty percent of the support for the ongoing research projects should be from the NIADDK and the remainder should be highly relevant to the overall goal of the Core Center grant. Foreign institutions are not eligible for this award. As the Centers Program develops, some attention will be given to program balance with respect to scientific area.

NIADDK expects to award 2 to 3 DDCC grants in Fiscal Year 1985 on a competitive basis. An average Center may include about 10 to 12 pilot/feasibility projects and 6 to 8 core units with a direct cost of up to approximately \$500,000. However, the actual size of the Center will vary depending on the needs of the Center. The anticipated awards are contingent upon the availability of appropriated funds which are designated for Centers. The general description of a Core Center, copies of Core Center Guidelines, and consultation may be obtained from:

Dr. Kirt Vener
Esophageal, Gastric and
Colonic Diseases Program
NIADDK
Bethesda, Maryland 20205

Dr. G.G. Roussos
Intestinal and Pancreatic
Diseases Program
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7821

Telephone: (301) 496-7121

Dr. Sarah C. Kalser
Liver and Biliary Diseases Program
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7858

Applications for grants for Digestive Diseases Core Centers will be evaluated in national competition by the NIH grant peer review process. Applications will be reviewed initially by a special review committee convened by the NIADDK, and subsequently by the National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council. The special receipt date for submission is November 16, 1984, with earliest funding August 1985.

ANNOUNCEMENTREQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA84-CA-10THE MODIFICATION OF EATING BEHAVIOR AND CANCER PREVENTION

P.T. 34; K.W. 0202022, 0411005, 0400000, 1200080

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: October 15, 1984
Application Receipt Date: November 15, 1984

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support research aimed at developing and implementing methods and strategies for dietary behavior modification for chronic risk reduction. The specific objectives will be reduction of dietary fat, increase of dietary fiber, a combination of these two or other dietary modifications associated with a reduction in risk of disease.

Interdisciplinary applications are invited to develop and implement innovative methods and strategies for changing dietary behavior, apply these methods on target populations to test their effectiveness for long-term adherence, and assess the actual dietary intake at baseline and at subsequent intervals as a test of change of nutrient intake. Special emphasis is placed on feasibility of approaches, sampling problems, study design, messages used, and expected results for long-term behavioral change.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. As more completely described in the RFA, the recipients will have primary responsibility for the development and conduct of the research with cooperation and assistance from NCI staff.

Inquiries and requests for the full text of the RFA may be directed to:

Ritva R. Butrum, Ph.D.
Diet and Cancer Branch
DCPC, NCI, NIH
Blair Building
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8753

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA
REDUCTION IN AVOIDABLE MORTALITY FROM CANCERS

84-CA-13

P.T. 34; K.W. 1002014, 0701042, 0411005

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1984
Letters of Intent Receipt Date: September 15, 1984

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites grant applications from investigators interested in developing intervention projects to reduce avoidable mortality from cancers.

The goal of this RFA is to identify and remedy key factors that contribute to avoidable mortality from specific cancer sites in defined populations. The focus of the RFA is limited to patterns of medical care use and provision. Studies related to primary prevention of cancer (e.g., prevention of smoking) are funded elsewhere in DCPC and will not be supported by this RFA. The investigators will: 1) determine the cancer site(s) that is to be studied; 2) identify factors that contribute to avoidable mortality for that cancer site in cases drawn from a defined population; 3) implement an intervention program to reduce mortality from the identified site; 4) evaluate the results of the intervention program in the defined population; and 5) identify prototype approaches to the reduction of avoidable mortality based on the findings of this project.

Applicants are strongly encouraged to submit a letter of intent and consult with NCI program staff before submitting an application because of the need for a clear understanding of the cancer control research issues involved and to facilitate planning for the review of applications.

Nonprofit and for profit institutions within the United States are eligible to apply for project periods of up to five years. It is anticipated that a maximum of five awards will be made as a result of this RFA.

Copies of the complete RFA may be obtained from:

Knut Ringen, Dr. P.H.
Cancer Control Applications Branch, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 4A01
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8597

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HD-07

NORMAL AND ABNORMAL LIMB DEVELOPMENT STUDIES

P.T. 34; K.W. 0404004, 1201270, 0701005, 1200840, 1200460

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: November 15, 1984

The Genetics and Teratology Section of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites research grant applications for basic and clinical studies on the normal and abnormal development of the limb.

I. BACKGROUND

Developmentally-caused limb malformations constitute severe birth defects that occur in at least 1 out of every 200 newborn infants and pose severe life-long suffering and morbidity for many afflicted individuals. Limb defects can include a decrease or absence of bones, amputation, polydactyly, syndactyly, congenital contractures, or aberrant development of muscle. They may result from structural, functional, or biochemical anomalies that are initiated during prenatal stages of development and are recognized at birth or in later life. The basis of some limb defects is genetic, but factors in the intrauterine environment, as well as exogenous drugs and chemicals can contribute to limb malformations. In many cases, the etiology of limb defects is still unknown. NICHD now encourages a new emphasis on basic biological investigations combined with clinical studies which should lead to prevention of developmentally-caused limb deformities in the future.

II. RESEARCH GOALS AND SCOPE

This RFA solicits applications from qualified investigators for studies on the normal and abnormal development of the limb covering the earliest developmental period through maturity of the extremity. Genetic and developmental biological approaches as well as techniques of experimental teratology may be used to explore limb developmental events. This would include, among other studies, gene regulatory investigations of the various macromolecular components of the

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

developing limb as well as investigations on determination and an elucidation of cell and tissue interactions necessary for differentiation of specific limb tissues such as cartilage or muscle. It would also entail studies on abnormal limb developmental processes caused by various etiological factors. Studies of clinical parameters are encouraged such as the usefulness and safety of new and existing medical technologies to monitor normal and abnormal limb development, as well as the development of improved prenatal diagnoses of limb malformations, e.g. using recombinant DNA technology. Human and other mammalian models are preferred in these investigations, but nonmammalian models that contribute to our knowledge of limb maturation and the production of developmentally-caused limb deformities in the human are also sought.

III. STAFF CONTACT

For further information, and a copy of the RFA contact:

Anne K. Krey
or
Delbert H. Dayton, M.D.
Genetics and Teratology Section
Clinical Nutrition and Early Development Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-5575

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-21

APPLICATION OF RECOMBINANT DNA TECHNOLOGY TO DIAGNOSIS OF CANCER

P.T. 34; K.W. 1201190, 1200370, 1002014, 1002008

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 30, 1984

The Division of Cancer Biology and Diagnosis (DCBD) of the National Cancer Institute (NCI), is inviting grant applications from interested investigators to search for new applications of recent advances in recombinant DNA technology for the diagnosis of patients with cancer. The development of molecular approaches to the identification of malignant and premalignant cells may result in earlier detection of the disease, lead to improved methods for classification of tumors, and improve the accuracy of cancer diagnosis.

This type of solicitation (the RFA) is issued to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Support for such awards is through the customary NIH grant-in-aid and is governed by the policies applicable to such grants. All applications in response to the RFA will be reviewed by an appropriate peer review group of NIH.

The present RFA announcement is for a single competition with a specified deadline of November 30, 1984, for receipt of applications.

I. BACKGROUND INFORMATION

The DCBD has a major responsibility to support research designed to improve the detection and diagnosis of cancer. The current state of the art in molecular genetics and recombinant DNA technology and the relatively little attention directed to clinical diagnosis using this technology make it important to encourage research on applications of this technology to cancer diagnosis. In this RFA, the program is expressing interest in grant applications proposing new approaches to diagnosis of cancer exploiting cellular changes at the molecular level.

II. MECHANISMS OF SUPPORT

The support mechanism for this program will be the traditional NIH grant-in-aid. Applicants will plan and execute their own programs. Approximately \$600,000 will be set aside to fund applications which are submitted in response to the RFA. It is anticipated that four to five applications can be funded. These applications will not compete for funding within the general pool of dollars available for other investigator-initiated research proposals. However, all applications received will

be evaluated by the rigorous standards of study section review. The expected starting date is July 1, 1985. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon availability of funds appropriated for fiscal year 1985. Only applications of sufficiently high scientific merit will be funded.

III. INQUIRIES

A copy of the complete RFA describing the research goals and scope, the review criteria and the method of applying can be obtained by contacting:

Sheila E. Taube, Ph.D.
Chief, Biochemical Diagnosis Section
Diagnosis Branch
Division of Cancer Biology and Diagnosis
National Cancer Institute
Westwood Building - Room 10A15
Bethesda, Maryland 20205

Inquiries concerning this announcement are encouraged and should be directed to Dr. Sheila E. Taube at the above address (Phone: (301) 496-7147). The program would appreciate the opportunity to clarify any issues or questions from potential applicants.

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFACOOPERATIVE AGREEMENTS FOR NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS84-CA-22

P.T. 34; K.W. 1200260, 1200180, 1003012, 1003002, 1200720, 1002008, 1002014, 0701038

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 14, 1984

This announces reissuance of an RFA announced in the NIH Guide for Grants and Contracts, Vol. 12, No. 7, July 15, 1983.

SUMMARY

Exciting leads in molecular biology, medicinal and organic chemistry, biochemistry, and pharmacology present unprecedented opportunities for design and pre-clinical evaluation of powerful new entities and strategies for the treatment of cancer. Exploitation of these leads and their extrapolation to new treatments can be accomplished by mobilizing the most creative scientists in a number of scientific disciplines regardless of their organizational affiliation. The NCDDG program will assist these scientists to interact, with NCI support, as a unit. It is envisioned that each NCDDG will be multi-disciplinary and multi-institutional; and will consist of a Group Director and a number of Program Leaders. The Group Director will be responsible for the application and for performance of the Group and will be accountable for funds awarded. Thus, each NCDDG will have capacity to generate new inventions, to translate rapidly their concepts into new treatments, to conduct preclinical biological, biochemical, and/or pharmacological testing pertinent to the selection of new treatment entities worthy of development to the clinic.

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The nature of NCI staff participation is included in the RFA. However, the applying Group must define its objectives in accord with its own interests and perceptions of novel approaches to the discovery of more effective cancer treatment. The role of NCI staff will be to provide assistance, advice, and guidance via information input at Group meetings. Final decision-making authority during performance will rest with the Group Director.

NCI hopes to make multiple awards for project periods of five year and has set aside \$1,500,000 for the initial year's funding.

The RFA is available from:

Dr. John M. Venditti, Ph.D.
Chief, Drug Evaluation Branch
Division of Cancer Treatment
National Cancer Institute
Landow Building - Room 5C03
Bethesda, Maryland 20205

Telephone: (301) - 496-8752

ANNOUNCEMENT

SMALL GRANT AWARD FOR PILOT PROJECTS

P.T. 34; K.W. 1200410, 0404002, 0701042, 1201230, 0202022

NATIONAL INSTITUTE ON AGING

Application receipt dates: October 1, February 1, June 1

The National Institute on Aging (NIA) is announcing a Small Grant Award for selected categories of research (noted below) beginning with the October 1, 1984 application receipt date. This announcement solicits applications for Small Grants pilot projects and supersedes the prior NIA small grants announcement (NIH Guide to Grants and Contracts, Vol. 10, No. 12, November 6, 1981).

I. RESEARCH SCOPE

Categories of research are limited to the following six areas:

A. Animal Models

Two types of animal models are acceptable: models to study intrinsic aging processes and models to study processes that give rise to diseases associated with aging. Areas of special interest include:

1. Studies which identify, define, characterize, or evaluate mammalian model systems for the study of normal comparative aging changes.
2. Studies of age-associated pathologic lesions in mammalian models that may simulate or replicate aging processes.
3. Studies of mammalian models which evaluate genetic or environmental effects on survival and/or aging.

Staff Contact: Dr. Richard Sprott
Building 31 - Room 5C-19
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-6402

This program is described in the Catalog of Federal Domestic Assistance No. 13.866, Aging Research. Awards will be made under the authority of Public Health Service Act, Section 301 (P.L. 78-410, as amended; 41 USC 241) and administered under HHS grant policies and Federal Regulations 41 CFR Part 52 and 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

B. Exercise Physiology

The areas of special interest are:

1. Studies to elucidate how mechanisms for biologic adaptation to exercise (acute and chronic) are influenced by the aging process.
2. Studies to define quantitatively the criteria by which the prescription of exercise is formulated to fulfill individual needs of healthy elderly.
3. Studies to demonstrate the role and mechanism of regular physical activity in preventing age-related disorders (e.g., hypertension, type II diabetes mellitus, osteoporosis).
4. Studies to assess the role of acute or chronic exercise in the regulation of immunologic phenomena involved in resisting and recovering from infectious diseases.

Staff Contact: Dr. William Kachadorian
Building 31 - Room 5C-27
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-9350

C. Senile Dementia of the Alzheimer Type

Studies to elucidate the etiology of pathogenesis of Alzheimer's disease, improved diagnosis and effective therapeutic interventions are of particular interest to NIA.

Staff Contact: Dr. Zaven Khachaturian
Building 31 - Room 5C-27
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-9350

D. Geriatric Medicine

The areas of special interest are:

1. Infectious Diseases: Research on the epidemiology, etiology, prevention, diagnostic evaluation, and treatment of infectious diseases in the elderly. Basic and clinical studies in microbiology, virology, immunology, and other types of research on this problem are encouraged. See NIA's announcement (NIH Guide for Grants and Contracts: Vol. 11, No. 12, page 17, November 5, 1982) for a more detailed description of NIA's research interests in infectious diseases in the elderly.

2. Urinary Incontinence: Research on the epidemiology, etiology, pathophysiology, diagnostic evaluation, and treatment of urinary incontinence in the elderly. Neurobiologic, pharmacologic, physiologic, urologic, behavioral, and other types of research on this problem are encouraged. See NIA's announcement (NIH Guide for Grants and Contracts: Vol. 10, No. 10, page 18, September 4, 1981) for a more detailed description of NIA's research interests in urinary incontinence in the elderly.

Applications on other geriatric research topics will be accepted at subsequent deadlines.

Staff Contact: Dr. Evan Hadley
 Building 31 - Room 5C-21
 National Institute on Aging
 National Institutes of Health
 Bethesda, Maryland 20205

Telephone: (301) 496-6761

E. Nutrition and Health of the Aged Adult

The areas of special interest are:

1. Age-related changes which affect nutrient requirements or nutrient status, including change in nutrient ingestion, absorption and utilization.
2. Nutrition-disease interaction in the elderly.
3. Effect of long-term drug use on nutritional status.

Staff Contact: Dr. Zaven Khachaturian
 Building 31 - Room 5C-27
 National Institute on Aging
 National Institutes of Health
 Bethesda, Maryland 20205

Telephone: (301) 496-9350

F. Health and Effective Functioning in the Middle and Later Years

For a description of this topical area, see NIH Guide for Grants and Contracts, Vol. 12, No. 6, June 17, 1983, pp. 10-15, and Vol. 12, No. 11, November 11, 1983. The areas of special interest are:

1. Linkages between particular psychosocial variables and the development of disease and disability.
2. Psychosocial factors in restoration of functioning or reversal of common forms of disability in old age (e.g., in chronic ill health, cognitive and motor performance).
3. Psychosocial interventions in maintenance of functioning and productivity at work or in the household.

Staff Contact: Ms. Kathleen Bond
 Building 31 - Room 4C-32
 National Institute on Aging
 National Institutes of Health
 Bethesda, Maryland 20205

Telephone: (301) 496-3136

II. PURPOSE OF AWARD

This is a one-year, non-renewable award intended to provide support for pilot projects, testing of new techniques, or feasibility studies of innovative and high-risk research which would provide a basis for more extended research.

III. ELIGIBLE APPLICANTS

This program is intended primarily for:

- A. Clinicians with limited research experience.
- B. Recently trained or less experienced investigators.
- C. Investigators who have interrupted their research careers and intend to resume them.
- D. Investigators changing field of research.
- E. Investigators at minority institutions or located in a largely non-research environment.
- F. Established investigators needing prompt support for a pilot project to maintain research momentum and productivity.

The award may not be used to supplement support for an ongoing project nor to provide interim support for projects under review by the Public Health Service.

IV. TERMS OF THE AWARD

The award will provide a maximum of \$15,000 (direct costs) for technical assistance, supplies, small equipment, and travel required by the project.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be submitted on Form PHS 398, available at most institutional business offices or from the Division of Research Grants, NIH. Special supplementary instructions required for use by applicants for the NIA Small Grants Program must be obtained from the NIA Staff Contacts listed above. An accelerated review will be scheduled as follows:

<u>Receipt Date</u> <u>Annually</u>	<u>Institute Committee</u> <u>Review</u>	<u>Council</u> <u>Review</u>	<u>Earliest Date</u> <u>for Funding</u>
Oct. 1, 1984	Nov/Dec 1984	Jan/Feb 1985	Feb 1985
Feb 1, 1985	March 1985	May 1985	June 1985
Jun 1, 1985	Jul 1985	Sept 1985	October 1985

(First receipt date for NIA is October 1, 1984)

Subsequent research topics will be announced at a later date.

VI. REVIEW CRITERIA

Applications will be evaluated with respect to the following criteria:

The significance and scientific merit of the proposed project, and its characterization as an innovative and/or pilot project which provides a basis for more extended research; the methodology; the investigator's background and training for carrying out the project; adequacy of the available and requested facilities, and the adequacy of justifications presented for budget requests.

For information regarding review of applications, contact:

Associate Director, OPEA
Attention: Scientific Review Office
National Institute on Aging
Building 31 - Room 5C-12
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-9666

ANNOUNCEMENT

INDIVIDUAL PREDOCTORAL RESEARCH

FELLOWSHIP FOR ONCOLOGY NURSES

P.T. 22; K.W. 1200950, 0701032, 1200170

NATIONAL CANCER INSTITUTE

Annual Application Receipt Date: February 1

I. BACKGROUND INFORMATION

The National Cancer Institute (NCI) invites competition for Predoctoral Research Fellowship Awards for Oncology Nurses. Applicants are restricted to those holding, at a minimum, a baccalaureate in nursing, and a license to practice nursing. Also, they must be accepted for training at the postbaccalaureate level in a program designed to culminate in the receipt of a doctor of philosophy degree, and must have identified preceptors who will guide their research training. Up to three awards will be made the first year, with the program leveling off at a total of ten active fellowships. These awards will be made only for long-term research training in any of the basic or applied sciences.

II. OBJECTIVES OF THE AWARD

This program is intended to encourage selected oncology nurses to prepare for academic research careers. The award will enable trainees to undertake up to five years of special study and supervised research experience tailored to individual needs with a sponsor (or sponsors) highly competent in the proposed area of research and research training. This award is intended to support the awardee during study and research towards the Ph.D. degree in a basic or applied cancer science.

III. CRITERIA FOR THE INDIVIDUAL PREDOCTORAL RESEARCH FELLOWSHIP FOR ONCOLOGY NURSES

Competitive review for these awards will assess the plans of (A) the applicant, and (B) the resources of the training institution.

A. THE APPLICANT MUST:

1. Hold at a minimum a baccalaureate of science in nursing from an accredited institution and be accepted in a program designed to culminate in the receipt of a doctor of philosophy degree.
2. Have demonstrated evidence of research interests and a potential for and a commitment to an academic career and have demonstrated evidence of scholarship and analytical ability.
3. Describe in reasonable detail the proposed research training project.

4. Be a United States citizen or national, or be admitted to this country as a permanent resident.
5. Free to inform the NCI annually for a period of five years, subsequent to completion of study, about academic status, publications, and research activities.

B. THE INSTITUTION MUST:

1. Be a domestic university with strong, well-established research training, and with adequate numbers of highly trained faculty in the pertinent clinical and basic science departments.
2. Provide quality facilities, resources, and opportunities necessary to the applicants research training plan.
3. Have sponsors with significant research support and proven capabilities in research training.
4. Endorse a training plan congruent with post-training plans of the applicant.

IV. AWARD

A stipend of \$5,292 and the sum of \$3,000 will be provided annually for partial defrayment of training-related expenses.

V. REVIEW OF APPLICATIONS

Applications for the Individual Predoctoral Research Fellowships for Oncology Nurses will be reviewed by an NIH peer review group and will be evaluated in terms of:

- A. The candidate's potential for and commitment to an academic career.
- B. The merits of the applicant's research training project.
- C. The proposed faculty's potential for training predoctoral oncology nurse fellows in the basic or applied sciences related to cancer.
- D. The quality of the training resources and training plan.
- E. The past research training experiences and present research support of the sponsor (or sponsors).

VI. HOW TO APPLY

- A. Use the Public Health Service Individual National Research Service Award application form (PHS-416-1) and send it to:

The Division of Research Grants
National Institutes of Health
Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Applicants are requested to send a brief "Letter of Intent" to reply to this announcement and should include name and address, preceptor's name and address, and the proposed area of research training to:

Program Director
NRSA Fellowships Program
Cancer Training Branch
Division of Cancer Prevention
and Control
Blair Building - Room 428
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8866

- B. The annual receipt date for these applications will be February 1. Applications will not be accepted after that date.
- C. The earliest begin date for funding should be July 1.
- D. Application forms (PHS-416-1) may be obtained from the institution's application control office. If not otherwise available, they can be requested from:

Office of Grants Inquires
Division of Research Grants
National Institutes of Health
Westwood Building - 448
5333 Westbard Avenue
Bethesda, Maryland 20205

- E. Type the phrase "**National Cancer Institute Individual Predoctoral Research Fellowship for Oncology Nurses**" on the front page of the application.

ANNOUNCEMENT

PHYSICAL ACTIVITY IN PREGNANCY

P.T. 34; K.W. 1201070, 1002034, 0701027, 1200240, 0202022, 0404019, 1200780

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The National Institute of Child Health and Human Development (NICHD) supports a wide range of research related to maternal health and the effects on the fetus and infant of pregnancy disorders and maternal health behaviors. Maternal physical activity is a variable of fundamental importance, and is of increasing clinical concern because of the expanded participation of women in the workplace and in sports. This program announcement is intended to focus investigator attention on this important area.

Very few carefully controlled observations have been made of human pregnancy to assess the benefits and possible adverse effects of various types and degrees of aerobic exercise. Animal studies have suggested mechanisms of possible detrimental effects of exercise to the fetus, but are of limited relevance to humans.

The purpose of this program announcement is to encourage submission of scientifically meritorious research grant applications in such areas as the following:

- (1) Prospective clinical studies of normal women regularly performing different levels of exercise during pregnancy, with careful specification of the nature, duration, and intensity of exercise and their relationship to outcome of pregnancy.
- (2) The effects of maternal exercise on fetal and placental growth, and on neonatal and infant health.
- (3) The alterations in metabolic, hormonal, and hemodynamic responses of normal women to sustained exercise testing at various times in pregnancy.
- (4) The interrelationships between maternal exercise and such interacting variables as maternal blood volume, environmental temperature/humidity, nutritional status, and complications of pregnancy, such as anemia and hypertension.
- (5) The particular benefits or risks to pregnancy outcome of exercise by women with various disorders of pregnancy.

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- (6) Safe techniques to measure uterine blood flow changes and fetal heart rate responses during maternal exercise in humans.
- (7) The interrelationships between maternal exercise and such other health behaviors as diet, smoking, and alcohol use.
- (8) Animal studies to define the specific changes in fetal metabolism, placental transport, fetal hormone synthesis and activity, and fetal temperature that may be induced by maternal exercise.

The above topics are examples and proposed research need not be limited to them.

APPLICATION SUBMISSION AND REVIEW

Applicants should use the regular research grant application form PHS-398, which is available at institutional grants offices or from the Division of Research Grants (DRG) NIH. Application receipt dates for new applications are: November 1, March 1, and July 1.

In order to identify the response to this announcement, check "yes" and put "Physical Activity in Pregnancy" under item 2 on page 1 of Form 398 of grant applications relating to the content of this announcement. Completed applications should be mailed to:

Division of Research Grants
National Institute of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

In accordance with existing NIH procedure, the DRG will assign each application to the appropriate study section for review.

Applications submitted in response to this announcement will be considered for funding under the regular research grant program without special set-aside funds.

Additional programmatic information may be obtained from:

Donald McNellis, M.D.
Special Assistant for Obstetrics
Pregnancy and Perinatology Section
CNED, CRMC, NICHD
National Institutes of Health
Landow Building - Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-5575

ANNOUNCEMENT

CLINICAL INVESTIGATOR DEVELOPMENT AWARD

P.T. 34, 44; K.W. 1200270, 0701007, 1002030, 0701013, 1200550

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) announces the availability of a Clinical Investigator Development Award (CIDA). This award, a career development award, replaces the NINCDS Teacher Investigator Development Award which has been offered since 1970.

The intent of the NINCDS through this mechanism is to prepare clinically-trained persons for academic research careers in the medical sciences related to the neurological and communicative disorders. The award bridges the gap between postdoctoral training and a secure academic appointment and completes the development of research capability of a candidate who already has some research experience.

Amount of Award - This career development award provides a stipend of up to \$40,000 per year. Since salary levels are set by the sponsoring institution, it is permissible to supplement the CIDA stipend with non-Federal funds to an amount consistent with the usual scale for other individuals at the grantee institution with similar experience and responsibility.

A research allowance of up to \$10,000 in the first and last years and of up to \$20,000 in the middle years of the CIDA may be requested. The research allowance will be awarded in amounts justified in the application and consistent with the recommendations of the initial review group and the National Advisory Neurological and Communicative Disorders and Stroke Council.

Duration of Award - The usual duration of award will be five years; however, this award provides the flexibility of 3 to 5 years of support for candidates who have prior research experience, as outlined below.

Eligibility -

M.D - (or other health professional degree, e.g., D.D.S., D.O., D.V.M) with or without M.S., M.P.H., Dr.P.H. and/or Ph.D. degrees.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.853, Stroke, Nervous System Trauma. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- o Candidates having completed residency training. Applicant organizations may propose a program of development of 3, 4, or 5 consecutive years. If requesting less than 5 years of support, the application must provide sufficient details about relevant past research experience to assure reviewers that the intended academic development could be accomplished in the proposed time frame.
- o Candidates within the residency training period, or those who have not had residency training. In all cases, at least two years of post-M.D. experience in clinical or basic science areas is a prerequisite. Programs may be proposed for a continuous 3-to-5 year period, or as a split award in which Part A (two consecutive years) may be separated from Part B (up to three consecutive years). Part A can provide for a 2-year period of research training usually in a basic science environment; Part B can provide for a 3-year period of sponsored research experience. Parts A and B may be separated by a period not exceeding 2 years. Parts A and B must both be proposed in the initial application when such a split award is contemplated.

Ph.D with professional experience in clinical areas (e.g., speech pathology; audiology; neuropathology; epidemiology).

- o Candidates must have at least two years of postdoctoral experience. Applicant organizations may propose a program of development of 3, 4, or 5 consecutive years. If requesting less than five years of support, the application must provide sufficient details about relevant past research experience to assure reviewers that the intended academic development could be accomplished in the proposed time frame.

Development Plan - The candidate's academic research development plan should include research and research training requiring at least 75% of time and effort. Related clinical and teaching activities not to exceed 25% time and effort may be requested, but must be described in the proposal.

Application Schedule - Receipt dates for applications are February 1, June 1, and October 1. Initial review will be by an NINCDS initial review group, with secondary review by the National Advisory Neurological and Communicative Disorders and Stroke Council. Earliest award dates will be approximately nine months after initial receipt. The first receipt date for the CIDA applications will be October 1, 1984. Applications for the former program, the Teacher Investigator Development Award, will not be accepted after the October 1, 1984 receipt date.

This announcement is not intended to provide all the details needed to apply for the CIDA. For further information about this program, including guidelines, details of the application process, and application instructions, please contact:

Donald H. Luecke, M.D.
Deputy Director, Extramural Activities Program
National Institute of Neurological and
Communicative Disorders and Stroke
National Institutes of Health
1016 Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-4188

ANNOUNCEMENT

RESEARCH GRANTS ON STATUS EPILEPTICUS

P.T. 34; K.W. 1200330, 1200460, 0701013, 0701042, 0415000, 1200370, 1200900

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application Receipt Date: November 1, March 1, and July 1.

I. INTRODUCTION

The Epilepsy Branch, Convulsive, Developmental, and Neuromuscular Disorder Program, National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) encourages the submission of research project grant applications (ROI) related to etiology, characterization, treatment, consequences, and prevention of status epilepticus.

II. BACKGROUND

Status epilepticus is defined as "epileptic seizures that are so frequently repeated or prolonged as to create a fixed and lasting epileptic condition." Status epilepticus is of significant clinical concern because of its high mortality and morbidity rates and its serious neurological consequences. In addition to tonic-clonic status epilepticus and epilepsy partialis continua, prolonged states of nonconvulsive absence and complex partial seizures have been accepted as forms of status epilepticus. Recent advances in documentation of prolonged seizures by closed-circuit television and electroencephalography and a new understanding of the cellular and knowledge and identified a number of areas in which knowledge of the disorder is far from complete.

III. RESEARCH GOALS

The goals of this research program are to obtain an understanding of all aspects of status epilepticus: its definition, etiology, incidence, treatment, consequences, and prevention. The research scope of this program encompasses both animal and human studies, utilizing a variety of experimental approaches and methods. Proposals with new ideas and initiatives would be welcome.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853, Clinical Basis Research, NINCDS. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

Examples of areas of potential research would include studies on the effects of repeated seizures on glial and synaptic function, biochemical regulators, receptors, amino acid neurotransmitters, and regional glucose metabolism. The cellular and molecular mechanisms that transform a single seizure into status epilepticus are not known. Additional drugs with greater efficacy and safety for treatment of convulsive status epilepticus need to be developed. Controlled comparisons of the drugs used to treat convulsive status have been limited in scope, and the preferred general anesthetic needs better definition. Electroclinical documentation and classification of neonatal status epilepticus needs to be done.

Research efforts to provide answers to these and other questions about status epilepticus are requested.

IV. MECHANISM OF SUPPORT

Support for this program will be through the traditional research grant-in-aid. Successful applicants will direct and carry out the individual research projects.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS 398 according to instructions contained in the application kit. Application kits are available from most institutional business offices or may be obtained from the Division of Research Grants at the address given below.

Check "yes" in item two on the face sheet of the application and type "Grants Related to Status Epilepticus" in the space provided.

Applications must be responsive to the program announcement. They will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants. A second level of review will be made by the National Advisory Neurological and Communicative Disorders and Stroke Council.

Deadlines for the receipt of applications are: November 1, March 1, and July 1.

The original and six copies of the application should be mailed to the following address:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

For further information applicants may contact:

James J. Cereghino, M.D.
National Institutes of Health
NINCDS, CDNDP, EB
Federal Building - Room 114
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1917

ANNOUNCEMENT

RESEARCH ON DIGESTIVE DISEASES

P.T. 34, 22; K.W. 1200400, 1201030, 1201080, 0202022, 1200670, 1002023, 1201300

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTES OF HEALTH

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

I. INTRODUCTION

The Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), The National Institutes of Health (NIH), and the National Center for Health Services Research (NCHSR) announce research and research career development grant support opportunities in the normal function and the diseases and disorders of the digestive system. The topics were selected and developed by committees of basic and clinical science experts for the National Digestive Diseases Advisory Board (NDDAB). These experts were charged by the NDDAB to recommend clinically important areas that are on the frontiers of research, but not fully exploited by the biomedical research community. Grant support for these research opportunities is offered through the programs of ADAMHA, NIH, and NCHSR (see section IV). Copies of the NDDAB report, Research Advances, Opportunities, and Needs in Digestive Diseases are available (see III, below).

II. RESEARCH GOALS AND SCOPE

Participating Institutes are encouraging applications for research and research career development grants in areas recommended by the NDDAB. Specifically, applications are encouraged in the areas listed below. Each of these topics is extensively developed in the NDDAB report, and interested persons are encouraged to obtain copies of the report. (Institutes with programs related to each topic are indicated following each area item used below. The first-listed institute is suggested as an initial contact point should you be unsure of an appropriate institute for your interests--see section IV for explanation of acronyms).

This announcement is an activity managed by the Digestive Diseases Intergency Coordinating Committee. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 403 (Public Law 78-410, as amended; 42 USC 284) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- A. Gastrointestinal Development (NICHD; also NIAAA, NIADDK, and NIDR).
- B. The Physiological Basis of Gastrointestinal Function (NICHD; also NCI, NIA, NIAAA, NIADDK and NIDR).
- C. Smooth Muscle Disease and Motility (NIADDK; also NIA, and NICHD).
- D. Gastrointestinal Regulatory Peptides (NIADDK; also NCI, NICHD, and NIDA).
- E. Prostaglandins (NIADDK; also NCI, NIAAA, and NICHD).
- F. Immunology of the Gastrointestinal Tract (NIAID; also NCI, NIA, NIAAA, NICHD, and NIDR).
- G. Nutrition (NIADDK; also NCI, NIA, NIAAA, NIDA, NICHD, NIMH, and NIEHS).
- H. Infectious Diarrheal Diseases (NIADDK; also NIA, NIAID, and NICHD).
- I. Viral Hepatitis (NCI; also NIAID, NIADDK, and NICHD).
- J. Liver Detoxification (NIADDK; also NCI, NIAAA, NICHD, and NIDA).
- K. Liver Transplantation (NIADDK; also NCI, NCHSR, NIAAA, NIAID, and NICHD).
- L. Gallstone Disease (NIADDK).
- M. Gastrointestinal Precancerous Conditions (NCI; also NIAID, and NIADDK).
- N. Gastrointestinal Endoscopy (NIADDK; also NCI, NCHSR, NIA, and NICHD).

The Fogarty International Center (FIC) and the Division of Research Resources (DRR) of the NIH have programs which relate to the above topics as follows:

- o The FIC International Research Fellowship Program provides the opportunity for foreign postdoctoral biomedical and behavioral scientists to gain further research experience in the laboratory of a U. S. scientist. The FIC Senior International Fellowship Program provides U. S. biomedical and behavioral scientists opportunity to go abroad to study and share their expertise.
- o Clinicians receiving research funding through the programs participating in this announcement, and requiring hospital beds, can utilize the resources of the General Clinical Research Centers (GCRCs) supported by DRR. The mechanism to do this is application through the GCRC Advisory Committee of institutions which are recipients of GCRC awards.

III. REQUESTING COPIES OF THE NDDAB RESEARCH REPORT

Individual copies of the NDDAB report "Research Advances, Opportunities and Needs in Digestive Diseases". U.S. Department of Health and Human Services (DHHS), NIH Publication No. 84-2658, October 1983 are available by writing:

Executive Director
National Digestive Diseases Advisory Board
P. O. Box 30377
Bethesda, Maryland 20814

IV. U S. PUBLIC HEALTH SERVICE PARTICIPATION IN THIS ANNOUNCEMENT

The Institutes listed below are participating in this announcement. A contact person is named for each Institute. Inquiries on grant applications and related matters are welcome and encouraged. See section II for suggestions of appropriate Institute relationships to announcement topics.

National Cancer Institute (NCI):

Dr. Andrew Chiarodo
Chief, Organ Systems Section
Cancer Centers Branch
National Cancer Institute
Blair Building - Room 722
Bethesda, Maryland 20205

Telephone: (301) 427-8818

National Center for Health Services Research (NCHSR):

Mr. Gerald S. Cohen
Chief, Medical Information System
National Center for Health Services Research
Park Building 318 No. 2
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-2080

National Institute on Alcohol Abuse and Alcoholism (NIAAA):

Dr. Norman Chang
Health Science Administrator
National Institute of Alcohol Abuse and Alcoholism
Parklawn Building - Room 14C17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4223

National Institute of Allergy and Infectious Diseases
(NIAID):

Dr. Richard E. Horton
Medical Officer
Clinical and Epidemiological Studies Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and Infectious Diseases
Building 31 - Room 7A49
Bethesda, Maryland 20205

Telephone: (301) 496-5893

National Institute of Arthritis, Diabetes, and Digestive
and Kidney Diseases (NIADDK):

Dr. Donald G. Murphy
Director, Special Emphasis Areas Program
Division of Digestive Diseases and Nutrition
National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases
Westwood Building - Room 3A15
Bethesda, Maryland 20205

Telephone: (301) 496-7455

National Institute of Child Health and Human
Development (NICHD):

Dr. Thorsten A. Fjellstedt
Health Scientist Administrator
National Institute of Child Health and Human
Development
Landow Building - Room 7C17
Bethesda, Maryland 20205

Telephone: (301) 496-5575

National Institute of Dental Research (NIDR):

Dr. Samuel Kakehashi
Health Science Administrator
Periodontal and Soft Tissue Diseases Branch
National Institute of Dental Research
Westwood Building - Room 519
Bethesda, Maryland 20205

Telephone: (301) 496-7784

National Institute on Drug Abuse (NIDA):

Dr. Stephen Szara
Chief, Biomedical Branch
Division of Preclinical Research
National Institute on Drug Abuse
Parklawn Building - Room 10A31
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-6300

National Institute of Environmental Health Sciences
(NIEHS):

Dr. Wilford S. Nusser
Associate Director, Extramural Programs
National Institute of Environmental Health
Sciences
P.O. Box 12233, Mail Drop T10
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-7723

National Institute on Aging (NIA):

Dr. Evan Hadley
Chief, Geriatrics Branch
National Institute on Aging
Building 31 - Room 5C21
Bethesda, Maryland 20205

Telephone: (301) 496-1033

National Institute of Mental Health (NIMH):

Dr. Ellen S. Stover
Chief, Research Resources Branch
National Institute of Mental Health
Parklawn Building - Room 10-104
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4337

Division of Research Resources (DRR):

Dr. Eric Elliot
Medical Officer
General Clinical Research Centers Program
Division of Research Resources
Building 31 - Room 5B47
Bethesda, Maryland 20205

Telephone: (301) 496-6595

Fogarty International Center (FIC):

Dr. Bettie J. Graham
Chief, International Research and Awards Branch
Fogarty International Center
Building 38A - Room 613A
Bethesda, Maryland 20205

Telephone: (301) 496-6688

V. MECHANISMS OF SUPPORT

The mechanism of support for this program will be the grant-in-aid, including, but not limited to, the traditional project grant, fellowships, new investigator research award, clinical investigator research award, physician scientist award, and research career development award. Potential applicants should acquaint themselves with the requirements of awards in which they have an interest. The regulations (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this program announcement is contingent upon availability of funds.

VI. METHOD AND CRITERIA OF REVIEW

- A. Assignment of Applications: Applications will be received by the Division of Research Grants (DRG), NIH, referred to an appropriate study section for scientific review, and assigned to individual Institutes of the participating agencies for possible funding (where appropriate dual interest assignments will be made). These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.
- B. Review Procedures: Applications in response to this announcement will be reviewed on a nationwide basis in competition with other applications received in the same review cycle, and in accord with the usual NIH/ADAMHA/NCHSR peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following study section review, the application will be evaluated by the appropriate Institute Advisory Council or Board with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by NIH/ADAMHA/NCHSR for regular research grant applications will prevail.

- C. Deadlines: Applications will be accepted in accordance with the usual PHS receipt dates. For further information, please contact the appropriate staff person.

VII. METHOD OF APPLYING

Research project grant applications should be submitted on forms PHS 398, which are available in the business or grants and contracts office at most academic and research institutions. The phrase "**Prepared in Response to PHS Program Announcement for Research on Digestive Diseases**" should be typed into item 2 of the first page of the application. Information on applications for fellowships, career development awards, other grant mechanisms, and current program emphases should be obtained directly from institute contact persons.

The completed original and six (6) copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact one or more of the Institute contact persons listed above.

ANNOUNCEMENT

CHILD AND ADOLESCENT MENTAL HEALTH RESEARCH AND RESEARCH TRAINING

P.T. 34, 441 K.W. 0701029, 0404004, 0701013, 0404000, 1002030, 0701042, 0701026

NATIONAL INSTITUTE OF MENTAL HEALTH

The National Institute of Mental Health (NIMH) has issued an announcement of Support for Child and Adolescent Mental Health Research and Research Training. NIMH seeks, through this announcement, to encourage basic, clinical, and applied research and research training in child and adolescent mental health and mental and emotional disorders. Such activity reflects a recognition that the advancement of child mental health requires increased understanding of normal and pathological processes as they operate and interact throughout the developmental stages leading to maturity in both males and females

Research and research training concerning children and adolescents are supported across the range of NIMH programs in the neurosciences, behavioral sciences, epidemiology, and clinical, treatment, prevention, and services research. Through the understanding of processes fundamental to mental health and mental health disorders in the formative years, there will be enhanced ability to promote normal child and adolescent development, to prevent the onset of mental disorders, and to treat the disorders when they occur.

Support is provided for investigating, and for training to investigate, processes on many levels from the molecular and cellular to the intrapsychic and interpersonal. Research may employ theoretical, laboratory, clinical, methodological, and field studies, any of which may involve clinical, subclinical, and normal subjects, as well as animal models appropriate to the system being investigated and the state of the field. Also research that crosses boundaries and/or brings expertise from one area to bear on another is encouraged.

The announcement sets out in detail the specific goals and requirements of the many child and adolescent research and research training programs in the Institute.

Applications submitted under this announcement will compete for funding with applications submitted under all NIMH research grant and research training programs.

For single copies of this announcement and for further information, contact:

Michael E. Fishman, M.D.
Assistant Director for Children and Youth
National Institute of Mental Health
Parklawn Building - Room 17C-20
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: 301 - 443-4580

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NIH Guide for Grants and Contracts

Vol. 13, No. 10, September 7, 1984

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AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

SIGNATURE REQUIREMENTS FOR NIH GRANT APPLICATIONS

This notice is both a reminder and a restatement of the National Institutes of Health (NIH) policy published in the August 14, 1970 issue of the "NIH Guide for Grants and Contracts" concerning applicant signature requirements for all NIH grant applications.

To be valid and acceptable for review, an application must have been properly executed by: 1) the proposed Principal Investigator and Program Director and 2) by an individual authorized to act for the applicant organization and to assume the obligations imposed by the requirements and conditions for any grant, including the applicable Federal Regulations.

"Per" signatures are not acceptable. If the official designated to sign for the applicant organization is not available to sign, an official authorized to act in his or her behalf may sign as "acting for" such official.

NOTICE

REVIEW PROCEDURES—REMINDER TO APPLICANTS

Sending Additional Materials for Your Grant Application:

If you need to send additional materials or corrections before your application has been reviewed by a study section or an initial review group, send these materials directly to the Executive Secretary of the group that will be reviewing your application. If you do not know the identity of the Executive Secretary or study section, send the material to:

Referral Section
Division of Research Grants
National Institutes of Health
Westwood Building - Room 248
Bethesda, Maryland 20205

Contacting NIH Staff after your Application has been Reviewed:

After your application has been reviewed by a study section or an initial review group, contact the appropriate program staff member of the funding Bureau, Institute, or Division for any information about your application. That person--not the Executive Secretary of the study section--is the appropriate source of information after the first level of review has been completed.

NOTICENIH/FDA REGIONAL WORKSHOPS - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0701028

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. The current schedule includes:

<u>DATE</u>	<u>LOCATION</u>	<u>CONTACT</u>
September 13-14, 1984	Stanford, CA	Ms. Phyllis S. Hall Human Subjects Coordinator Stanford University Encina Hall Stanford, CA. 94305 Telephone: (415) 497-3638
October 22-23, 1984	Washington, DC	Mrs. Lucille Holland Office of The Institutional Review Board Room 214, Annex 2 Freedman's Square Howard University Washington, DC 20059 Telephone: (202) 636-7812
January 17, 1985	Los Angeles, CA	Dr. Harry Neustein Professor of Pathology Chairman of Institutional Review Board Children's Hospital of Los Angeles 4650 Sunset Blvd. Los Angeles, CA 90054 Telephone: (213)359-8111

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A final list of dates and locations will be published at a later date. For further information regarding education programs contact:

Roberta H. Garfinkle
Office for Protection from Research Risks
National Institutes of Health
Building 31-Room 4B09
9000 Rockville Pike
Bethesda, MD 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-AM-05

AUTO-IMMUNITY RELATED TO ENDOCRINE DISEASES

P.T. 34; K.W. 1200050, 1200440

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt date: December 3, 1984
Letter of Intent Receipt date: November 15, 1984

The DEMD Division of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Child Health and Human Development (NICHD) announces the availability of a Request for Application (RFA) on the above subject. Copies of the RFA are currently available from the staff of the NIADDK.

This program will support research directed towards understanding the role of autoimmune antibodies in the manifestations of various endocrine diseases and the genetic factors involved, such as the relationships to the HLA antigens. The endocrine diseases will include Hashimoto's disease or primary myxedema, Grave's disease, idiopathic Addison's disease, adrenocortical insufficiency (Schmidt's Syndrome), primary ovarian failure, autoimmune testicular failure, idiopathic hypoparathyroidism, renal tubular acidosis, and autoimmunity associated with sterility in both men and women.

It is hoped that this announcement will be of particular interest to investigators in endocrinology, immunology, cell biology, membrane biochemistry, clinical endocrinology, pathology, epidemiology and genetics.

This program is described in the Catalog of Federal Domestic Assistance No. 13.847, Diabetes, Endocrinology and Metabolism; 13.855, Immunology, Allergic and Immunologic Diseases Program; and 13.865, Center for Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

The date for receipt of the applications will be December 3, 1984.

Request for copies of the RFA should be addressed to:

Robert A. Tolman, Ph.D.
Endocrinology Research Program Director
NIH, NIADDK, DEMD
Westwood Building - Room 626
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENTS ANNOUNCEMENTS: RFA

84-CA-19

STUDIES ON BOVINE LEUKEMIA

P.T. 34; K.W. 1002014, 1002008, 1002004

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1984

The Division of Cancer Etiology (DCE), National Cancer Institute (NCI), invites applications for cooperative agreements to support investigator-initiated research in bovine leukemia. Studies of interest include, but are not limited to: (1) research to determine the nature of the target cells that undergo neoplastic transformation in vivo in cattle and sheep; (2) investigations to search for and develop a sensitive lymphoid cell transformation assay in vitro and delineation of the cellular and molecular events that lead directly to the cell transformation event; (3) research to determine the nature of the different protein products of the viral genome, including those involved in cell transformation; (4) research to determine the nature of the transforming DNA sequences in BLV tumors and lymphocytes; (5) investigations on the BLV genome through nucleotide sequence analyses and comparison to the genomes of other retroviruses, including HTLV; (6) investigations to delineate the nature of the plasma blocking factor and its mode of regulation of the expression of BLV; and (7) investigations to determine the role of cellular immunity in infection and expression of disease.

Applicants funded under this RFA will be supported through the Cooperative Agreement mechanism. These are assistance relationships involving substantial involvement of NCI staff during the performance of the project. The nature of NCI staff participation is included in the RFA. The recipients will have primary responsibility for the development and conduct of research. NCI involvement will be in regard to coordinating and synthesizing the research effort in regard to approaches, methodologies, and exchange of information. The total project period for applications submitted in response to the present RFA should be three years. The intent is to fund approximately four to five projects with a total program cost for all Cooperative Agreements under this RFA equal to approximately \$500,000 of FY85 funds for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high merit. Although this program is included in the financial plans of the NCI, the awards pursuant to this RFA are contingent upon the availability of funds for this purpose. The issuance of this RFA does not represent a guarantee that any funds will be awarded. No funds are available for the purchase of large capital equipment.

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Copies of complete Request for Applications (RFA) and additional information may be obtained from:

Padman S. Sarma, D.V.M., Ph.D.
Program Director, RNA Virus Studies I
Biological Carcinogenesis Branch
Division of Cancer Etiology
Landow Building, Room 9A22
National Cancer Institute
Bethesda, Maryland 20205

Telephone: 301/496-9734

To ensure their review, applications should be received by November 15, 1984.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATION: RFA

84-CA-27

STUDIES ON HUMAN T CELL LEUKEMIA/LYMPHOMA VIRUS TYPES I & II (HTLV-I, HTLV-II)

P.T. 34; K.W. 1002045, 1201150, 1200650, 1201310

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1984

The Division of Cancer Etiology (DCE), National Cancer Institute (NCI), invites applications for cooperative agreements to support investigator initiated research on HTLV type I and II. Studies of interest include, but are not limited to: 1) investigation of the viral genome of various substrains of HTLV including studies of the LTR, env and pX regions; 2) identification and characterization of viral genome protein products as a clue to determining if they are transforming proteins and to understand the functional activity of the resultant products; 3) investigations of virus integration sites in various systems and/or hosts to determine if the transforming function acts in the cis or trans mode; 4) investigations directed to characterizing the clinically relevant biological activities of the virus, especially its immunosuppressive and/or immunoregulatory effects on the host; 5) determination of the exact mode of horizontal transmission of the virus, including investigations of possible insect transmission; 6) studies in virus-host interactions; including geographical localization, determination of host-range, endemic areas other than the Caribbean and Japan (i.e. Africa and Far East) and localization and overlap of different types of HTLV virus; 7) characterization of HTLV-like viruses of non-human primates and determination if there is an evolutionary link to HTLV; and 8) investigation of the possible use of vaccines to prevent or suppress the horizontally transmitted HTLV associated diseases.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. The recipients will have primary responsibility for the development and conduct of research. NCI involvement will be in regard to coordinating and synthesizing the research effort in regard to approaches, methodologies and exchange of information.

The total project period for applications submitted in response to the present RFA should be three years. The intent is to fund approximately five to seven projects with a total program cost for all Cooperative Agreements under this RFA equal to approximately \$750,000 of FY85 funds for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high merit. Although this program is included in

the financial plans of the NCI, the awards pursuant to this RFA are contingent upon the availability of funds for this purpose. The issuance of this RFA does not represent a guarantee that any funds will be awarded. No funds are available for the purchase of large capital equipment.

Copies of complete Request for Applications and additional information may be obtained from:

Padman S. Sarma, D.V.M., Ph.D.
Program Director, RNA Virus Studies I
Biological Carcinogenesis Branch
Division of Cancer Etiology
Landow Building - Room 9A22
National Cancer Institute
Bethesda, Maryland 20205

Telephone: 301/496-9734

To ensure their review, applications should be received by November 15, 1984.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA
84-CA-17

THE PHYSIOCHEMICAL EFFECTS OF DIETARY FIBER IN HUMANS

P.T. 34; K.W. 0202022, 1002014, 1002028, 1002034, 1200410

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: October 16, 1984
Application Receipt Date: December 11, 1984

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support research on the physical, chemical and biologic effects of dietary fibers and their possible protective role in carcinogenesis. Studies of potential interest to NCI include, but are not limited to, the effects of fiber on: (1) fecal mutagenic activity, (2) fecal content of bile acids, and (3) colon cell kinetics, morphology, and physiology. Investigators are encouraged to be creative and to explore novel physicochemical effects of various fiber fractions. While some of these studies can only be done in animal models, the intent is that results from these studies shall be directly related to human carcinogenesis.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. As more completely described later in the RFA, the recipients will have primary responsibility for the development and conduct of the research with cooperation and assistance from NCI staff.

Copies of the complete Request for Applications and additional information may be obtained from:

Elaine Lanza, Ph.D.
Diet and Cancer Branch
Blair Building - Room 619
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 427-8753

To ensure their review, applications should be received by December 11, 1984.

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA84-CA-18SELECTED CANCER PREVENTION CLINICAL TRIALS

P.T. 34; K.W. 1200180, 0202022, 0701042, 0411005

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 10, 1984

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support risk reduction clinical trials which are directed toward examining the role of various preventive agents and/or diet in the prevention of cancer. Studies of populations at increased risk to colon, breast, bladder, and head and neck cancer are particularly appropriate at this time. Studies of occupational cohorts who have been exposed to known initiators and/or promoters are also encouraged. Situations where the dose response to the promoter can be estimated are particularly relevant. Another category of possible prophylactic trials involve studies of populations at risk to second malignancies. For example a number of studies have reported that Hodgkin's disease patients treated with alkylating agents have an increased incidence of leukemia. Several trials involving skin and lung cancer risk reductions with carotenoids and retinoid compounds have been implemented and additional studies at these sites with the agents indicated are not encouraged at this time.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. As more completely described in the RFA, the recipients will have primary responsibility for the development and conduct of the research. Programmatic involvement by the Government will be in the form of: (1) NCI assistance with the FDA in securing INDs, if required, (2) safety toxicity review, (3) safety monitoring in cases when the NCI is the IND sponsor, (4) assistance from NCI staff relating to drug availability, and (5) review of clinical laboratory quality assurance activities in the assay of collected sera if necessary.

The terms of award of these cooperative agreements will detail the Government involvement and will specify the level of NCI program assistance and cooperation.

Copies of the complete Request for Applications and additional Information may be obtained from:

Mary Ann Sestili, Ph.D.
Chemoprevention Branch
Blair Building - Room 616
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 427-8643

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA84-CA-24

P.T. 34; K.W. 1200250, 1200410, 1200130, 1200490, 1002023

USE OF ONCOGENE RELATED PRODUCTS FOR CANCER THERAPY

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 14, 1984

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites grant applications from interested investigators for basic and applied studies to evaluate the therapeutic efficacy of oncogene-related products in animal tumor models.

I. BACKGROUND

Biological response modifiers refers to agents or approaches that alter the relationship between tumor and host by modifying the host's biological response to tumor cells, with a resultant therapeutic benefit. The application of these agents with a primary intent of therapy is the major focus of the Biological Response Modifiers Program.

The components of the BRM program include immunoaugmenting, immunomodulating and immunorestorative agents, interferons and interferon inducers, lymphokines, cytokines, antigrowth factors, thymic factors, tumor antigens and modifiers of tumor antigens on cell membranes, antitumor antibodies, antitumor cells, maturation, differentiation and tumor growth factors.

This RFA addresses use of oncogene and oncogene-related products for cancer therapy in animal models. A number of cellular genes collectively called "proto" oncogenes have been identified which are involved in the control of cellular proliferation and differentiation and have been shown to be direct mediators of cell transformation. Activation of these cellular genes as oncogenes appears to play an important role in both initiation and maintenance of oncogenesis. Several "proto" oncogenes have been identified in the human genome and a number of these have been found to be expressed in the activated form in various human tumors. In tissue culture, inhibition of oncogene activity appears to be associated, in several instances, with reversion of the transformed state. Where functional products of oncogenes have been described, they have been localized to the cell membrane, cytoskeletal elements, or the nucleus. These all represent areas where alterations might be expected to lead to the expression of a malignant phenotype, such as lack of contact inhibition and uncontrolled cell division. Expansion of knowledge of how biological response modifiers and oncogenes interact through investigator initiated research could provide useful information for the future understanding of how oncogenesis is initiated and maintained and how immunity may be enhanced towards specific oncogene induced malignancies.

II. OBJECTIVES AND SCOPE

This Request for Applications (RFA) is intended to stimulate research that will develop and utilize oncogene products or reagents made against these products for therapy in animal model systems. Development of oncogene or oncogene-related products for therapeutic evaluation may involve use of tumor associated membrane antigens for monoclonal antibody production and development of vaccines, use of monoclonal antibodies directed against growth factors or growth factor receptors controlled by or encoded by oncogenes or analysis of factors that inhibit the action of oncogene products that control cell division. Other reasonable approaches directed toward cancer therapy employing oncogene or oncogene-related products or related reagents with antitumor potential may be proposed. Studies may involve the isolation and characterization of these products for the purpose of evaluating their ability to modify or alter tumor initiation, growth and/or metastases as well as stimulating cytotoxicity in vivo or in vitro through activation of macrophages, cytotoxic T cells or natural killer cells. Additional proposals involving studies on how oncogene or oncogene-related products may interfere with specific immune functions will also be considered. Therapeutic potential may be evaluated in the treatment of transplanted, induced or spontaneous animal tumors or human tumor xenografts in nude athymic mice or rats.

III. STAFF CONTACT

For further information, and a copy of the RFA contact:

Dr. Cedric W. Long, Acting Chief
Biological Resources Branch
Biological Response Modifiers Program
Division of Cancer Treatment
National Cancer Institute
Frederick Cancer Research Facility
Building 426 - Room 1
Frederick, Maryland 21701

Telephone: (301) 695-1098

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-25

INNOVATIVE APPROACHES TO DEVELOPMENT OF CANCER CHEMOPREVENTIVE AGENTS

P.T. 34; K.W. 1002014, 1200250, 0701038, 1200420

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 15, 1984

I. BACKGROUND

The Division of Cancer Etiology (DCE) of the National Cancer Institute (NCI) invites investigator-initiated research grant applications for basic studies emphasizing innovative approaches to the inhibition and/or suppression of carcinogenesis. These studies are especially needed since strategies for cancer prevention involving reduction or elimination of human exposure to environmental carcinogens may not always be possible, and since significant portions of the human cancer burden may be due to endogenous carcinogens, cocarcinogens, and promoters. Inhibition of the development of cancer by administration of chemical, biochemical, and biological compounds, which directly and/or indirectly inhibit the cancer-producing effects of neoplastic and promoting substances, is well known in animal systems and may offer an alternate approach to human cancer prevention. Especially important in these new approaches, regardless of preventive agent(s) employed, will be deep inquiries into the mechanisms of anticarcinogenesis which take full cognizance of the developing forefronts of molecular biology and carcinogenesis, cellular biology, mechanisms of carcinogenesis and genetic aspects of carcinogenesis such as genetic susceptibility and resistance in experimental animal systems (including known, well-defined systems of "spontaneous" tumorigenesis).

II. OBJECTIVES AND SCOPE

Research conducted under this RFA seeks innovative approaches that will expand basic knowledge and understanding of the role and mechanism(s) of action of chemopreventive agents in modulating the carcinogenic process. Specifically, this RFA seeks high quality, innovative approaches, with agents of the applicants' choosing, which will emphasize any of the following areas:

- A. Thorough studies on mechanisms of action. Studies are needed from both in vitro and in vivo perspectives.

- B. The pharmacokinetics of promising agents should be established for optimizing dose and delivery schedule in chemoprevention and for deriving basic understandings of the absorption, distribution, metabolism and excretion of these agents during the course of chemoprevention.
- C. Structure activity relationships of promising compounds should be investigated.
- D. Comparative studies on pathways of metabolism should be pursued in human vs animal systems in view of possible differences in biohandling and response.
- E. Compounds showing particular promise in short-term assays require animal studies to investigate their efficacy as blocking and/or suppressing agents of the carcinogenic process. In these animal studies, dose and pharmacokinetics vs. response relationships should be derived for those compounds demonstrating anticarcinogenic effectiveness. Investigations should develop time/response relationships for efficacy as well.
- F. Toxicologic investigations coupled with appropriate metabolic and pharmacokinetics studies should be pursued on these blocking and/or suppressive compounds.

III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed four years. The intent is to fund multiple projects, with total costs amounting to approximately \$1.0 million for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

The present RFA announcement is for a single competition with a specified deadline of December 15, 1984, for receipt of applications.

IV. COPIES OF THE RFA MAY BE OBTAINED FROM:

Dr. Carl E. Smith
Program Director
Chemical and Physical Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9B06
Bethesda, Maryland 20205

Telephone: (301) 496-4141

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA84-CA-26MUTAGENS IN HUMAN FOODS

P.T. 34; K.W. 1002028, 0202022, 1002014

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 15, 1984

The Division of Cancer Etiology (DCE) of the National Cancer Institute (NCI) invites grant applications from interested investigators for basic studies intended to provide insights and approaches to an understanding of the possible role of food mutagens in human cancer causation.

I. BACKGROUND

Concern over the presence of mutagens in human foods is part of a large and growing interest in the role of diet in human cancer causation and in the possible inhibition of cancer by dietary means. In this context, the relevance of dietary mutagens derives from their genotoxic effects which could lead to cancer induction. Concern over dietary mutagens gains further emphasis from the widespread occurrence of mutagens in human foods. Apart from the well-publicized association of mutagens with charcoal-broiled steak, mutagen formation has been reported to occur upon the boiling of beef stock, the broiling of hamburgers at a relatively modest surface temperature, the frying of potatoes, and the toasting of bread. Mutagens have also been found to be present in many vegetables, in alcoholic beverages, spices, coffee, and tea. Various contaminants may also constitute a source of mutagens present in human foods. According to one estimate, the foods and beverages ingested by an individual in the course of a single day might contain 1-2 grams of mutagens.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to accelerate the development of additional understanding relative to the possible role, fate, and cancer relevance of known dietary mutagens commonly present in human foods. Applications submitted in response to this RFA should be responsive to one or more of the items selected from any one or from a combination of the following categories:

- A. In depth, basic studies on a small number of mutagens selected from among those which are known to occur naturally in human foods, those found in human feces, and those human dietary mutagens the formation of which is associated with the processing and preparation of food; compounds of particular interest include, but are not limited to, the following six classes: (1) heteroaromatic amines of the carboline and imidoquinoline types (2)

hydroxylated flavonoids (3) carbonyl compounds such as acrolein, malonaldehyde and methylglyoxal (4) fecapentaenes (5) endogenous N-nitroso compounds and (6) aromatic hydrocarbons.

- B. Development of analytical procedures for the quantitation of the foregoing mutagens in foods and for the quantitation of them and their respective metabolic products present in blood, body fluids and tissues, and feces.
- C. In vitro and in vivo studies relative to the absorption, metabolism, and possible carcinogenicity of selected compounds such as quercetin and the human fecapentaenes. However, full scale animal bioassays will not be supported through this announcement.

III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health research project grant and all policies and requirements which normally govern the grant programs of the PHS apply. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed four years. The intent is to fund multiple individual research project grants with total costs amounting to approximately \$750,000 for the first year.

The present RFA announcement is for a single competition with a specified deadline of December 15, 1984, for receipt of applications.

IV. INQUIRIES

Copies of the RFA may be obtained from:

Dr. David G. Longfellow
Acting Chief
Chemical and Physical Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9A02
Bethesda, Maryland 20205

Telephone: (301) 496-5471

ANNOUNCEMENT

AVAILABILITY FOR REQUEST FOR APPLICATIONS: RFA

84-HL-16H

NATIONAL RESEARCH AND DEMONSTRATION CENTERS ON ISCHEMIC HEART DISEASE

P.T. 04; K.W. 1200240, 1200230, 0403004

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: December 3, 1984

The National Heart, Lung, and Blood Institute (NHLBI) announces its intent to solicit grant applications from the current Specialized Centers of Research (SCORs) on Ischemic Heart Disease in a single competition for designation as National Research and Demonstration Centers (NRDCs). To apply for this program, current SCOR grantees will be asked to submit competing supplemental applications that detail plans for demonstration and education research activities that are thematically related to ischemic heart disease and for core activities that will serve to coordinate and integrate the various components of the NRDCs.

A Request for Applications (RFA) has been issued to the current SCOR grantees in Ischemic Heart Disease. The application receipt date is December 3, 1984; after initial technical merit review these competing applications will be reviewed by the National Heart, Lung, and Blood Advisory Council in May 1985. The award date for successful applicants will be June 1, 1985; the duration of these supplemental grants will be approximately 4-1/2 years.

Although the competition is limited to current Ischemic Heart Disease SCOR grantees, other interested parties may receive an informational copy of the RFA by writing to the following:

Dr. Michael C. Lowe
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 3C06
Bethesda, Maryland 20205

Telephone: (301) 496-1081

The issuance of the RFA for NRDCs on Ischemic Heart Disease does not imply any intent to discontinue support for a separate and distinct Ischemic Heart Disease SCOR program. The NRDC and SCOR grant mechanisms of support, together with that of investigator-initiated research, training, and contract support, serve to promote the Institute's comprehensive research program; the support of each of these mechanisms will be continued.

ANNOUNCEMENT

GERIATRIC LEADERSHIP ACADEMIC AWARD (K07)

P,T. 34; K.W. 0404002, 0404000, 1200180, 0502000

NATIONAL INSTITUTE ON AGING

I. PURPOSE

The National Institute on Aging (NIA) invites academic health centers and other health professional schools to submit applications for the support of leadership activities in the development of research and research training programs in aging. (As used in this announcement, "aging" refers to all aspects of gerontology and geriatrics, i.e., biomedical, behavioral, and social aspects of aging and the special problems of older persons.) This Award is aimed at encouraging and assisting more health professional schools to increase their efforts in research and training in aging.

Priority is given to those academic centers or schools with limited activities in aging but which have a strong interest in, and commitment to, expanding their research and training efforts in aging. These awards offer opportunities for supporting start-up or expansion of such activities. Thus, this program is aimed at meeting needs which have not been met by other types of awards available from the NIA and other Federal agencies.

II. BACKGROUND

The Report on Education and Training in Geriatrics and Gerontology (submitted by the US Department of Health and Human Services (DHHS) to the Congress in February 1984) presents ten general principles identified by the DHHS Ad Hoc Committee on Enhancement of Training in Geriatrics and Gerontology and its expert consultants.

Among these principles are the following:

- o All students preparing for careers in the health and other human services professions should receive education about the aging process and the strengths and problems of the aged.
- o Health professional schools should have faculty with expertise in aging to conduct substantial and high-quality basic, graduate, and continuing education programs and to serve as role models.
- o Faculty members should have opportunities to engage in research on aging and the aged in order to maintain their expertise and expand the available body of knowledge.
- o Interdisciplinary experiences should be a regular and integral part of training programs in geriatrics and gerontology in light of the complex needs of many elderly persons.

- o Educational resources should be shared among schools at academic health centers and other university campuses to achieve maximum impact and avoid unnecessary duplication.

The Report also emphasizes the fact that information on the aging process and the elderly should be incorporated, as appropriate, throughout health profession curricula and clinical experiences; specialized courses should provide more intensive materials. The Report indicates that research on aging should be encouraged and enhanced in the many relevant disciplines and fields.

To achieve these objectives, there must be concentrated and coordinated efforts on the part of many faculty members and departments in various biomedical, behavioral, and social sciences and in numerous health professional schools. Experiences in other programs have demonstrated that these types of efforts can be assisted and strengthened when responsibilities for leadership are assigned to a designated faculty member who has the active support of the principal officials of the institution.

III. PROGRAM OBJECTIVES AND ELIGIBILITY CRITERIA

The objectives of this program are to help strengthen the capacities of health professional educational institutions to incorporate information and instruction on aging throughout their curricula and to encourage and enhance research and training activities related to aging.

A faculty leader is to be the focal point for developing and improving research and teaching in aging. The individual is to provide leadership and coordination, including such activities as encouraging and assisting other faculty members to integrate aging issues into their research and teaching, organizing and conducting studies and courses focused on aging, developing resources for aging research and teaching, and linking related activities among and within various health professional schools. The faculty leader should have the active and continuing support of the principal executive officials of the institution and should be at a level in the organization that indicates and encourages such interest and support (e.g., reporting to the Vice President for Health Affairs).

The faculty leader should have demonstrated competence and continuing interest in research and teaching on aging. A candidate with established research credentials but with limited background in geriatrics may qualify for appointment without the full range of skills provided a clearly described plan for acquiring them is incorporated in the application. The candidate should have sufficient stature, training, and experience so that no more than one year of intensive supplemental preparation is needed.

The institution's program may be based on one of a number of approaches in line with local circumstances. For example, one of the following approaches might be adopted:

- A. An academic health center program including all of the health professional schools of the institution.
- B. A program involving the medical school and one or more other health professional schools.

C. A program involving a single health professional school.

In all cases, the program should include a faculty committee with representation from the various participating schools and/or departments to work with the designated faculty leader in planning and developing research and training activities in aging.

Regardless of the type of overall approach selected, the following elements must be considered in each proposal:

The candidate must:

- o Have an appropriate academic appointment at the institution at the time the award is activated.
- o Have sufficient research experience and background in geriatrics and/or gerontology to be effective in developing and actively implementing a quality research and education program in geriatrics.
- o Specify a program for enhancing personal skills as needed.
- o Present a program for developing or improving geriatric research and education in the grantee institution and for evaluating the outcome of the effort.
- o Commit a substantial portion of effort to the proposed programs.
- o Agree to report annually on the status of the program.
- o Agree to meet annually with other recipients of Geriatric Leadership Academic Awards to exchange ideas, methods and program evaluations.

The institution must:

- o Name and sponsor a senior or mid-level faculty member with competence and a major career interest in geriatric research and related training programs. (The candidate must be a citizen, a noncitizen national of the U.S. or have been lawfully admitted to the U.S. for permanent residence.)
- o Present plans to develop or improve geriatric research and educational programs.
- o Identify and demonstrate availability of the resources (populations, patients, manpower, materials, equipment, laboratory facilities) necessary to implement the proposed program.
- o Provide the candidate with time to acquire the skills necessary for personal development and for the development of the geriatric research and training program.
- o Provide access to facilities for rigorous geriatric research.

- o Provide evidence of commitment from the administration and from the sponsoring departmental chairmen to implement the proposed program so that the geriatrics program is coordinate with other relevant research and training programs.
- o State the mechanisms for continued institutional support of the geriatric program.

IV. CONDITIONS OF THE AWARD

- A. Awards for up to three years; after competitive review, may be extended for one additional three-year period.
- B. A portion of the salary of the faculty leader and related fringe benefits, up to a maximum of \$40,000.
- C. Additional costs for the further preparation of the faculty leader in aging (not to exceed the equivalent of one year's training).
- D. Domestic travel expenses of the faculty leader and a limited number of other faculty members to attend professional meetings and an annual meeting of awardees.
- E. Limited secretarial support.
- F. Teaching aids.
- G. Indirect costs not to exceed 8 percent of the direct costs, exclusive of tuition fees and equipment expenditures
- H. Allowable direct costs not to exceed \$80,000 a year.

NOTE: These awards are not to replace current funding. In addition, investigators who have received the Geriatric Medicine Academic Award in the past are ineligible for this support.

V. REVIEW CRITERIA

The following characteristics will be considered:

- A. Commitment of the institution to strengthening research and educational activities in aging.
- B. Background and potential of the candidate as a leader in research and educational and clinical programs and as a teacher and research investigator.
- C. Merit of the institutional plan to strengthen research and training activities in aging beyond to the current status of activities and capacities
- D. Scope and nature of collaboration among participating schools and/or departments.

VI. REVIEW PROCESS AND METHOD OF APPLYING

Applications will receive technical review by an initial review committee appointed by the National Institute on Aging and secondary review by the National Advisory Council on Aging of the NIA.

Applications will be reviewed three times a year according to the following schedule:

<u>Applications Received by:</u>	<u>Council Review</u>	<u>Earliest Starting Date</u>
November 1	May	June 1*
February 1	Sept.	Oct. 1
June 1	Feb.	Mar. 1*

* of the year following receipt

Applicants are encouraged to discuss their plans and the evaluation criteria with, and direct any other inquiries to:

Associate Director
Biomedical Research and Clinical Medicine Program
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C09
Bethesda, Maryland 20205

Telephone: (301) 496-4996

or

Associate Director
Behavioral Sciences Research Program
National Institute on Aging
National Institutes of Health
Building 31 - Room 4C32
Bethesda, Maryland 20205

Telephone: (301) 496-3136

Application kits may be secured from, and submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

COMPLEMENTARY TRAINING AWARDS FOR RESEARCH ON AGING (T32)

P.T. 44; K.W. 0404002, 0404000, 1200170

NATIONAL INSTITUTE ON AGING

I. INTRODUCTION AND PURPOSE

The National Institute on Aging (NIA) invites complementary applications from well-established research training programs to train investigators in the biomedical, behavioral, or social aspects of the established program that are related to research on aging. This initiative is intended to encourage and assist these established programs to increase their efforts to train investigators for careers in aging and thus to increase the number of investigators trained in the aging aspects of related disciplines. (Aging, as used in this Announcement, refers to all aspects of gerontology and geriatrics, i.e., biomedical, behavioral, and social aspects of aging and the special problems of older persons.)

This announcement is in addition to and does not replace the previous NIA announcement regarding training programs in aging and geriatrics. Institutions with established research programs in aging or geriatrics are encouraged to consider applying for training program support as described in the previous announcement (NIH Guide for Grants and Contracts, Vol. 12, No. 3, March 25, 1983).

II. BACKGROUND

Research in aging encompasses a wide range of issues and complexities. In order to address these subjects effectively, investigators who have preparation in both the field of aging and a related scientific field or discipline are often required.

The Report on Education and Training in Geriatrics and Gerontology (US Department of Health and Human Services submitted to Congress in February 1984) pointed out that an effective method of preparing individuals for research in aging is to build upon the strengths and capacities of established training programs in related fields. Examples of the wide variety of fields in which such activities might be undertaken are programs in the neurosciences, clinical pharmacology, cognitive psychology, cell biology, sociology, and various disease-oriented research areas.

This approach recognizes and takes advantage of the relevance and resources of established research training programs in various scientific fields. It offers a unique opportunity to prepare individuals for research careers focused on aging issues. Such efforts can also further understanding and collaboration between the aging field and other scientific fields.

III. PROGRAM OBJECTIVES AND SPECIFIC REQUIREMENTS

The objective of these complementary awards is to assist strong, well-established research training programs in various scientific fields relevant to aging to expand their efforts in the preparation of more individuals who are interested in careers in aging-related research and education through an additional training program supported by the NIA.

The following elements must be considered in each proposal:

- A. Initiation by a strong, well-established research training program in a field relevant to aging.
- B. Administration by a program director interested in, and committed to, expanding the current program to give more attention and emphasis to aging-related training.
- C. Commitment of potential trainee(s) to careers with a major emphasis in aging-related research and training.
- D. Arrangements for the trainee(s) to be associated on a continuing basis with others working in the aging field at the sponsoring institution (or, in special circumstances, through agreement with another nearby institution).
- E. A career development plan indicating how the program director and trainee(s) will enhance research competencies in both aging and the specialized field of the sponsoring program during the training period, including active and ongoing participation in aging-related projects.

IV. APPLICANT ELIGIBILITY REQUIREMENTS:

Domestic nonprofit private or public institutions may apply for grants to support research training programs. The applicant institution must have, or be able to develop, the staff and facilities required for the proposed program.

Under certain conditions, the Secretary of Health and Human Services may extend the period for undertaking service or for repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual.

STIPENDS AND OTHER TRAINING COSTS: The current stipend level for predoctoral individuals at all levels of experience is \$5,292 per annum.

For postdoctorals, the stipend for the first year of support is determined by the number of years of relevant postdoctoral experience at time of appointment. Relevant experience may include research experience (including industrial), teaching, internship, residency, or other time spent in full-time studies in a health-related field beyond that of the qualifying doctoral degree. The stipend for each additional year of NRSA support is the next level on the stipend structure. Current postdoctoral stipends are as follows:

Years of Relevant Experience	Stipend
0	\$14,040
1	14,736
2	15,468
3	16,236
4	17,040
5	17,892
6	18,780
7 or more	19,716

NRSA stipends may be supplemented by an institution from non-Federal funds. No Federal funds may be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may the conditions of stipend supplementation detract from or prolong the training.

Tuition, fees, and medical insurance are allowable trainee costs if such charges are required of all persons in a similar training status at the institution, without regard to their source of support. Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program. Costs of trainee travel including attendance at scientific meetings which the institution determines to be necessary to the individual's training may be requested.

Institutional costs of up to \$1,500 per year per predoctoral trainee and up to \$2,500 per year per postdoctoral trainee may be requested to defray the costs of training-related expenses such as staff salaries, consultant costs, equipment, research supplies, staff travel, and other expenses. The availability of funds may modify the maximum levels of institutional costs awarded. An indirect cost allowance based on 8% of total allowable direct costs, or actual, whichever is less, may be requested. Applications from State and local government agencies may request full indirect cost reimbursement.

The training program director at the institution will be responsible for the selection and appointment of trainees to receive National Research Service Awards and for the overall direction of the program. The training program must provide opportunities for individuals to carry out supervised biomedical or behavioral research with the primary objective of extending their skills and knowledge. Special attention should be given to the appointment of minority students and women.

TRAINEE ELIGIBILITY REQUIREMENTS: The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Individuals on temporary or student visas are not eligible.

Predocotrual trainees must have received a baccalaureate degree as of the beginning date of their NRSA appointment, and must be training at the postbaccalaureate level in a program leading to the award of doctor of philosophy or science or equivalent degree. Individuals who wish to interrupt their medical, veterinary, dental, or other professional school studies for a

year or more to engage in full-time research training before completing their professional degrees are also eligible. National Research Service Awards may not support study leading to the M.D., D.O., D.D.S., or other similar professional degrees, nor may these awards support residency training.

Postdoctoral individuals must have received, as of the beginning date of the NRSA appointment, a Ph.D., M.D., D.O., D.D.S., D.M.D., D.V.M., O.D., D.P.H., Sc.D., Eng.D., Dr.P.H., D.N.S., or equivalent degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree granting institution that all degree requirements have been met is acceptable.

Trainees are required to pursue their research training on a full-time basis. Trainees in clinical areas are expected to confine clinical duties to those that are part of the research training.

PAYBACK PROVISIONS: Before individual trainees can be appointed to a training grant, they must sign an agreement that they will fulfill the NRSA payback requirements. Recipients agree to engage in biomedical or behavioral research and/or teaching for a period equal to the period of NRSA support in excess of 12 months. Once an individual has had 12 months of postbaccalaureate NRSA support, all subsequent NRSA support is subject to payback.

Recipients must begin to undertake the obligated service on a continuous basis within 2 years after termination of NRSA support. For individuals who fail to fulfill their obligation through service, the United States is entitled to recover the total amount paid to the individual for the obligated period plus interest. Financial payment must be completed within 3 years.

PERIOD OF SUPPORT: Institutional grants may be made for competitive segments of up to five years and are renewable. No individual trainee may receive more than five years of aggregate NRSA support at the predoctoral level and three years of aggregate NRSA support at the postdoctoral level including any combination of support from institutional and individual awards. Any exception to this policy requires a waiver from NIH.

REVIEW PROCESS: Applications are evaluated for scientific merit by an NIA initial review group based on the following criteria: the proposed research training objectives and program design, the qualifications of participating faculty, the previous training record of the research program and its ability to attract high caliber trainees, the availability of research support, the extent of the institutional commitment, and the available facilities. Applications are also reviewed by the National Advisory Council on Aging. Final selection will be made by the NIA based on the review group's recommendations, the need for research personnel in specified program areas, and the availability of funds. The BID will notify the applicant of the final action shortly after the meeting of the National Advisory Council on Aging.

V. REVIEW SCHEDULE:

<u>Application Receipt Date</u>	<u>Initial Review Meeting</u>	<u>Council/Board Meeting</u>	<u>Earliest Start Date</u>
February 1	June	September/October	December 1
June 1	October/November	January/February	April 1
October 1	February/March	May	July 1

VI. APPLICATION MATERIAL: Application must be made on Form PHS 6025-1. This form is usually available at institutional Offices of Sponsored Research, Grants and Contracts Offices or their equivalent. Applications are available also from the Office of Grants Inquiries, Division of Research Grants (DRG) NIH, Bethesda, Maryland 20205. A self-addressed mailing label will expedite handling.

Applicants are encouraged to discuss their plans and the evaluation criteria with, and direct any other inquiries to:

Associate Director
Biomedical Research and Clinical Medicine Program
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C09
Bethesda, Maryland 20205

Telephone: (301)496-4996

or

Associate Director
Behavioral Sciences Research Program
National Institute on Aging
National Institutes of Health
Building 31 - Room 4C32
Bethesda, Maryland 20205

Telephone: (301)496-3136

ANNOUNCEMENT

EPIDERMOLYSIS BULLOSA AND THE BIOLOGY OF THE BASEMENT MEMBRANE ZONE

P.T. 34; K.W. 1200750, 1002004, 1002010, 1002023, 1003002, 1201000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NATIONAL INSTITUTE OF DENTAL RESEARCH

The Skin Diseases Program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDDK), in cooperation with the National Institute of Child Health and Human Development (NICHD) and the National Institute of Dental Research (NIDR), is encouraging the submission of applications for research grants in epidermolysis bullosa (EB) and in studies of the basic biology of the cutaneous basement membrane zone (BMZ).

Epidermolysis bullosa is a group of hereditary diseases in which skin and other epithelial surfaces, including the mucous membrane of the gastrointestinal and respiratory tracts, form blisters and become denuded after physical trauma of varying degree. In many cases, symptoms of the diseases resemble severe burns. As many as 20 possibly genetically distinct forms of EB have been described. In its mildest form, blisters of EB may be confined to hands and feet. The dystrophic forms of EB, however, may show widespread blistering and skin erosions which heal slowly, if at all; and may result in severe pain, scarring, deformities, and contractures; malnutrition and anemia; and gastro-intestinal problems, corneal erosions, and dental problems. Severe forms of the disease may manifest themselves in utero and can result in premature death, often in infancy or childhood.

The basic underlying cause for the sensitivity of epidermolysis bullosa patients to physical trauma is unknown; it may differ in various genetic forms of the disease. It is thought, however, that the basic cause may involve either a structural defect in proteins or other components that bind epidermis to the underlying dermis, or an abnormal enzyme that degrades one or more of those structural elements. As a result, the attachment between epidermis and dermis is weakened.

Since the initial pathologic changes of EB appear to occur in the basement membrane zone, the NIADDDK and its collaborating Institutes, the NICHD and NIDR, seek studies

This program is described in the Catalog of Federal Domestic Assistance No. 13.846, Arthritis, Musculoskeletal and Skin Diseases, No. 13.865, Research for Mothers and Children, and No. 13.84., Periodontal Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

aimed at achieving a better understanding of pathophysiologic mechanisms and/or structural abnormalities which contribute to the onset of EB, as well as studies to gain further insight into the basic biology of the basement membrane zone. In addition to its clear importance to EB, research investigation of the basement membrane zone is directly relevant to other important areas of biomedical research, including burns, wound healing, development of artificial skin, the structure-function relationship of collagen and collagenolysis and their genetic control, and the biochemical basis of genetic and congenital abnormalities of the BMZ in the adult and at prenatal and subsequent developmental stages. Such determinations should provide the information on the underlying cause and ontogeny of different forms of epidermolysis bullosa on which alleviation, prevention, and treatment of these diseases could be based. Research proposals are encouraged that utilize research advances in genetics, pathology, cell and developmental biology, biochemistry, and immunology as they relate to various types of EB and to the biology of the basement membrane zone.

I. METHOD AND CRITERIA OF REVIEW

A. Assignment of Applications

Applications will be received by the NIH's Division of Research Grants (DRG) referred to an appropriate initial review group for scientific review, and assigned to the NIADDK, NICHD, or NIDR for possible funding. These decisions will be governed by programmatic considerations as specified in the DRG Referral Guidelines.

B. Review Procedures

Applications in response to this announcement will be reviewed in accord with the National Institutes of Health peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following initial review, the application will be evaluated for program relevance by the Advisory Council of the Institute to which the application is assigned. Review criteria customarily employed by the National Institutes of Health (NIH) for regular research grant applications will prevail. Approved applications will compete for available funds with other approved grant applications assigned to the NIADDK, NICHD, or NIDR.

C. Deadline

Applications will be accepted in accordance with the announced receipt dates for new applications (see receipt dates and review schedule in application kits).

D. Method of Applying

Applications for research grants should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. The phrase, **"PREPARED IN RESPONSE TO RESEARCH GRANTS ANNOUNCEMENT IN THE AREA OF EPIDERMOLYSIS BULLOSA AND BASEMENT MEMBRANE ZONE BIOLOGY"** should be typed across the top of the first page of the application.

The original and six copies of the application should be sent or delivered to:

Applications Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact the following program directors:

Alan N. Moshell, M.D.
Skin Diseases Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 405
Baltimore, Maryland 20205

Telephone: (301) 496-7326

Anne K. Krey
Health Scientist Administrator
Genetics and Teratology Section
National Institute of Child Health
and Human Development
Landow Building - Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-5575

Health Scientist Administrator
Periodontal & Soft Tissue Diseases Branch, EP
National Institute of Dental Research
Westwood Building - Room 519
Bethesda, Maryland 20205

Telephone: (301) 496-7784

ANNOUNCEMENTSEXUALLY TRANSMITTED DISEASES - RESEARCH ON CHLAMYDIAL INFECTIONS AND VAGINOSIS (VAGINITIS)

P.T. 34, 22; K.W. 1200670, 1201360, 1002023, 1201335

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for regular research grants for the purpose of conducting studies on the subjects of (a) chlamydial infections in males and females and (b) vaginosis (vaginitis). Applications for research in all areas of chlamydial infections and in vaginosis are encouraged through this announcement.

I. CHLAMYDIAL INFECTIONS**A. BACKGROUND**

Infections with *Chlamydia trachomatis* are now among the major sexually transmitted diseases in the U.S. and most other industrialized nations. Although firm data are lacking in the U.S., these infections probably supersede even gonorrhea as an overriding public health problem; estimates are that chlamydial infections in both males and females total over 3,000,000 cases annually. In males, the disease usually occurs as a mild urethritis. It is estimated, however, that epididymitis occurs in about one-half of the 500,000 cases of chlamydial infections in males. Epididymitis is a painful and serious sequela that can result in sterility. In females infected with chlamydial organisms, mucopurulent cervicitis, considered as a counterpart to urethritis in infected males, is being seen with increased frequency in STD clinics.

Chlamydial infections in females are even more important as a public health problem because of the increasing role of this agent in pelvic inflammatory disease (PID) and infertility. Estimates are that chlamydia are responsible for at least 20% of all PID cases in the U.S. In the absence of firm data, it is estimated that more than 200,000 women are hospitalized annually and another 1,000,000 are treated as out-patients. The costs to the health care system for this disease burden are enormous. Additionally, because of chlamydial infection, perhaps 11,000 women of child-bearing age are rendered involuntarily sterile owing to tubal damage, and another 3,600 will suffer ectopic pregnancies (with their associated risk of maternal death).

This program is described in the Catalog of Federal Domestic Assistance No. 13.856, Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 Public Law 78-410, as amended; (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Of the more than 150,000 infants born to chlamydia-infected women each year, perhaps 75,000 may develop conjunctivitis and 30,000 may develop pneumonia. In fact, this may be the most frequent cause of pneumonia in infants.

B. Research Needs and Opportunities

Some suggested areas of research are outlined here. These are not to be considered as excluding other areas where needs and opportunities also exist.

1. Rapid and specific diagnostic tests should be considered as an area of interest. A newly licensed rapid diagnostic test (the Microtrak system - SYVA Corporation) may be of great value in diagnosing patients with asymptomatic infections. Other tests, however, should be developed.
2. Expansion of knowledge on the basic biology and immunology of chlamydia is an urgent need, to increase understanding of the pathogenesis of chlamydial infections. This will include studies on: surface structures and functions; antigen characterization and isolation; host immune responses. The problem of persistent or chronic infections should form part of the research thrust.
3. Animal model systems are also an area of much needed research, to provide better understanding of the pathogenesis of genital infections and of PID in humans.
4. The role of chlamydia in perinatal disease and in complications of pregnancy needs further definition.

II. VAGINOSIS (VAGINITIS)

A. BACKGROUND

This syndrome, characterized by pruritis, pain, inflammation and discharge is considered to have a multiple etiology. The majority of these cases are caused by the protozoan trichomonas, by yeasts (candida species) and by a variety of other microorganisms, many of them uncharacterized. Surveys have ranked the vaginosis syndrome as among the ten most frequently encountered female disorders; these infections result in a significant proportion of visits by women to primary and specialty health care providers. In STD clinics, about one-third of the visits by women are owing to infectious vaginosis. Early estimates are that \$36 million is spent annually on treatment in STD clinics alone - this figure is very much higher if treatment by private physicians is included. The total impact in terms of cost of therapy, lost time from work, and personal suffering is indeed large. Knowledge and understanding of this syndrome lags far behind that of other sexually transmitted diseases.

It is only recently that a small number of investigators have begun to apply modern methods of microbiology, immunology and biochemistry to study this problem. Far greater efforts are required, however, to obtain the knowledge necessary to have a significant impact in controlling this complex syndrome.

Suggested areas of research needs and opportunities are briefly outlined below. These are provided primarily as guidelines, and are not to be considered as excluding other appropriate research areas.

B. Research Needs and Opportunities

1. Increasing understanding of the vaginal ecosystem. Multiple microbial species are involved and interact with one another and with the local environment, causing subtle changes associated with menstrual cycle phases, contraception, and possibly sexual activity. Study of the host immune responses and of the fundamental microbiology and biochemistry of the causal organisms provide wide opportunities for research.
2. Increased knowledge of trichomoniasis and development of newer methods of therapy are needed. The current treatment of choice is potentially toxic and drug resistant strains have also been reported. Alternative chemotherapies, virulence factors and host defenses are areas of research need.
3. Increased understanding of non-specific vaginitis is needed. The roles of *Gardnerella vaginalis*, other anaerobic bacteria, yeasts, and mycoplasmas need further clarification. Microbial synergism is not well understood in this milieu, particularly as related to etiology and pathogenesis.
4. The existence of recurrent or chronic disease, the nature of host immune responses, and the interaction of complex vaginal factors need clarification.

III. MECHANISMS OF SUPPORT

Research applications considered appropriate responses to this announcement include the traditional project grant (R01), the New Investigator Research Award (R23), and career development and research training applications. These can include the Career Development Award (K04), the Physician Scientist Award (K11), the Clinical Investigator Award (K08), and the Individual Post-doctoral Fellowship Award (F32). The specific application forms required are available from the Division of Research Grants (DRG) NIH.

Applications will receive competitive review by appropriate study sections of the Division of Research Grants and will be considered for funding by the Institute in competition with all other applications, based on scientific merit and the availability of funds. This is not a one-time announcement, but is a statement of continuing interest in these selected disease areas.

IV. METHOD OF APPLYING

Applicants are encouraged to advise the Institute of their intent to submit an application and to seek advice regarding the type of application and the nature of their intended research.

Application receipt dates, advisory council reviews, and dates of possible awards

are as presented in the information found in the application kits. These kits are available at most institutional business offices, or may be obtained from:

Office of Grant Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 448
Bethesda, Maryland 20205

Telephone: (301) 496-7441

On page one, item 2, of the application form, the word "Yes" and the title of this program announcement "**Research on Chlamydial Infections and Vaginosis**" should be typed.

The completed original and six (6) copies should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
5333 Westbard Avenue
Westwood Building - Room 240
Bethesda, Maryland 20205

VI. STAFF CONTACT

Request for information or advice should be directed to:

Milton Puziss, Ph.D.
Chief
Bacteriology and Virology Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and
Infectious Diseases
5333 Westbard Avenue
Westwood Building - Room 748
Bethesda, Maryland 20205

Telephone: (301) 496-7728

ANNOUNCEMENTSTUDIES OF DIABETES MELLITUS AND RELATED PROBLEMS

P.T. 34; K.W. 1200350, 1200770, 1200460, 1200240, 1201070, 1200190, 0701013

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE ON AGING

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NATIONAL INSTITUTE OF DENTAL RESEARCH

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

NATIONAL EYE INSTITUTE

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The above-named Institutes of the National Institutes of Health (NIH) invite applications for research grants in the general area of diabetes mellitus and related problems. Investigators working in other areas of research are particularly encouraged to develop diabetes-related projects either independently or, where appropriate, in collaboration with individuals currently engaged in diabetes research.

I. PROGRAM SPECIFICATIONS

A. Program Objectives

Diabetes mellitus and its complications are major public health problems in the United States today. The NIH and other organizations have attempted to stimulate research into the cause, cure and prevention of diabetes and its related endocrinologic and metabolic disorders during the past several years. The National Diabetes Advisory Board with financial support from various corporations, foundations, voluntary health agencies and the NIH, (including NEI, NIADDK, NICHHD, NHLBI, and NINCDS) recently sponsored a meeting, the Second National Diabetes Research Conference, to review the state-of-the-art in various areas of diabetes research, to identify and summarize progress which has been made since the last such meeting (1979), to identify current opportunities and needs and to make some priority recommendations for the next five years.

Awards will be made under the authority of the Public Health Service Act, Title III, Section 301, (Public Law 78 -410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

The purpose of this solicitation is to make the summary report from this meeting available to interested investigators in order to stimulate investigator-initiated applications in the perceived areas of need.

B. Research Scope

The emphasis of this solicitation is upon the research needs outlined in the Summary Report from the Second National Diabetes Research Conference.

The following list includes the areas of research recommended by the twelve conference workgroups:

- o Etiology and pathogenesis of IDDM
- o Etiology and pathogenesis of NIDDM
- o Cardiovascular Complications
- o Eye Complications
- o Neurological Complications
- o Kidney Complications
- o Insulin Biosynthesis and Gene Studies
- o Pregnancy
- o Insulin Secretion
- o Hormone Action
- o Transplantation
- o Insulin Delivery Systems
- o Dental Complications
- o Epidemiology

These recommendations are not necessarily all-inclusive and any new ideas with creditable hypotheses that would appropriately fall within the scope of diabetes-related research could be the basis for an application.

Copies of the Conference Report can be obtained upon request from:

The Diabetes Research Program
Westwood Building - Room 605
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20205

C. Mechanism of Support

The mechanism of support for this program will be the grant-in-aid (regular research grants - R01). The regulations (Code of Federal Regulations, Title 42, Part 52 and, as applicable to the state and local governments, Title 45, Part 74) and policies which govern the research grant programs of the NIH will prevail. The award of grants pursuant to this Program Announcement is contingent upon receipt of appropriated funds for this purpose.

II. METHOD AND CRITERIA OF REVIEW

A. Assignment of Applications

Applications will be received by the NIH Division of Research Grants (DRG) referred to an appropriate Study Section for scientific merit review, and assigned to individual Institutes (see page 1) for possible funding. Referral decisions will be governed by normal programmatic considerations as specified in the Referral Guidelines of the NIH DRG.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nation-wide basis in competition with other research grant applications, and in accord with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (Study Section), and then by the National Advisory Council of the appropriate Institute(s). The review criteria customarily employed by the NIH for regular research grant applications will prevail.

C. Deadline

Applications will be accepted in accordance with the usual NIH receipt dates for new applications as follows:

<u>APPLICATION RECEIPT</u>	<u>INITIAL REVIEW</u>	<u>COUNCIL REVIEW</u>	<u>EARLIEST START DATE</u>
March 1	June	Sept./Oct.	December 1
July 1	Oct./Nov.	Jan./Feb.*	April 1*
November 1	Feb./March*	May*	July 1

*of the year following application receipt.

III. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. On the face page of form PHS 398, indicate that the application was prepared in response to the Program Announcement entitled "**Studies of Diabetes Mellitus and Related Problems**". The original and six copies of the application should be sent or delivered to:

Application Receipt
 Division of Research Grants
 National Institutes of Health
 Westwood Building - Room 240
 Bethesda, Maryland 20205

For further information, investigators are encouraged to contact one or more of the following individuals:

National Institute of Arthritis, Diabetes, and Kidney and Digestive Diseases

Diabetes Research Program Director
NIADDK-DEMD-DPB
Westwood Building - Room 605
Bethesda, Maryland 20205

Telephone: (301) 496-7731

National Institute on Aging

Chief, Geriatrics Branch
Extramural and Collaborative Research Program
NIA
Building 31 - Room 5C21
Bethesda, Maryland 20205

Telephone: (301) 496-1033

National Institute of Allergy and Infectious Diseases

Medical Officer, Clinical
and Epidemiology Studies Branch
NIAID
Building 31 - Room 749
Bethesda, Maryland 20205

Telephone: (301) 496-5893

National Institute of Child Health and Human Development

Chief, Clinical Nutrition
and Early Development
NICHD
Landow Building - Room 7C17
Bethesda, Maryland 20205

Telephone: (301) 496-5575

National Institute of Dental Research

Deputy Associate Director
NIDR Extramural Programs
Westwood Building - Room 504
Bethesda, Maryland 20205

Telephone: (301) 496-7748

National Institute of Environmental Health Sciences

Associate Director for Extramural Program

NIEHS

Building 31 - Room 2B55

Bethesda, Maryland 20205

Telephone: (301) 496-3511

National Eye Institute

Chief, Retinal and Choroidal Diseases Branch

NEI

Building 31 - Room 6A52

Bethesda, Maryland 20205

Telephone: (301) 496-5983

Further information on research opportunities in the NEI may be obtained by requesting the Institute's Research Plan entitled "Vision Research: National Plan 1983-84" from:

Office of Program Planning and Evaluation

NEI

Building 31 - Room: 6A25,

Bethesda, Maryland 20205.

National Heart, Lung and Blood Institute

Associate Director

Arteriosclerosis, Hypertension

and Lipid Metabolism Program

Division of Heart and Vascular Diseases

NHLBI

Federal Building - Room 412C

Bethesda, Maryland 20205

Telephone: (301) 496-1613

National Institute of Neurological and Communicative Disorders and Stroke

Director, Convulsive, Developmental,

and Neuromuscular Disorders Program

Federal Building - Room 812

Bethesda, Maryland 20205

Telephone: (301) 496-6541

ANNOUNCEMENTPHASE I/II CLINICAL EVALUATION OF VIRAL ONCOLYSATES PREPARED AGAINST HUMAN TUMORS - BIOLOGICAL RESPONSE MODIFIERS RESEARCH

P.T. 34; K.W. 1200280, 1200130, 1002023, 1002045

NATIONAL CANCER INSTITUTE

Application Receipt Dates: November 1, March 1, July 1

The National Cancer Institute's (NCI) Division of Cancer Treatment (DCT) desires to expand its support of clinical treatment research. The program is seeking applications for research grants concerned with the Phase I/II Evaluation of Viral Oncolysates Prepared Against Human Tumors. In making this program announcement it is not the intent of the NCI to make or imply any delimitation related to biological response modifiers research, but rather to stimulate investigator initiated research in biological response modifiers related to cancer therapy.

Innocation of normal animals with lysates formed by infection of syngeneic tumor cells with certain viruses can provide a high degree of resistance against subsequent engraftment of uninfected tumor cells. Viral oncolysates can be formed either in the animal or in tissue culture. Uninfected tumor cell homogenates, viral particles, or mixtures of the two were not protective; it appears that active viral infection of the tumor cell is necessary to provide subsequent tumor resistance. Several animal tumor model systems have been described using a variety of viruses as well as tumors. Recently, a few preliminary clinical trials have been reported showing some evidence of tumor control. The BRMP wishes to verify and extend these observations to determine the therapeutic value of this approach for cancer treatment.

Applications in response to this announcement will be reviewed in accordance with the usual National Institutes of Health (NIH) peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board. The review criteria customarily employed by the NIH for regular research grant applications will prevail. All PHS and NIH grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this program announcement.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402(Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

DEADLINE

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates are: November 1, March 1, July 1.

METHOD OF APPLYING

Non-profit organizations and institutions, governments and their agencies, for profit organizations, and individuals are eligible to apply. Applications should be submitted on form PHS 398, which is available in the grants and contracts business office at most academic and research institutions or from the Office of Grants Inquiries, Division of Research Grants (DRG), NIH. In space #2 on the first page of this form, indicate the title of the Program Announcement.

Additionally, a brief covering letter should accompany the application indicating it is being submitted in response to this program announcement. The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact:

Dr. Cedric W. Long, Acting Chief
Biological Resources Branch
Biological Response Modifiers Program
Division of Cancer Treatment
National Cancer Institute
Frederick Cancer Research Facility
Building 426 - Room 1
Frederick, Maryland 21701

Telephone: (301) 695-1098

In order to alert the DCT to the submission of applications with primary thrust directed to biological response modifiers research, a copy of the covering letter should be sent under separate cover to Dr. Long.

1

2 Austin, F. and Boone, C. *Advances in Cancer Research*. 30, 301, 1979.

Cassell, W., Murray, D. and Phillips, H. *Cancer*, 52, 856, 1983.

NIH LIBRARY



3 1496 00131 6960

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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

LIBRARY

Vol. 13, No. 11, October 12, 1984

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

Ultracentrifuge Safety Notice from Beckman Instruments
Dated June 22, 1984

P.T. 18; K.W. 0701034, 1014002

This important safety letter, mailed by Beckman Instruments to all ultracentrifuge owners, contains reclassification information on all of the older Model L, Model L2, Model L3 and Model L4 series of ultracentrifuges, and to owners of Type 35 or Type 42 rotors below Serial Number 1299. The letter contains information on two recent chemical explosions and the steps which Beckman is taking to eliminate the possibility of these potentially dangerous explosions occurring in the future. These steps on the older instruments (15 years old or older) are the elimination of the centrifuge/rotor combination which could trigger a secondary chemical failure. If you have a Beckman ultracentrifuge of the type listed above, and have not received the letter, contact Beckman Spinco Division (415) 857-1150, Ext. 1506 or 1702.

At the beginning of August representatives of the Spinco Division of Beckman Instruments visited the NIH to provide a fuller explanation of secondary chemical failures than was possible in their recent letter. This situation analysis was presented to Administrative, Safety and Research personnel. Also outlined were the financial programs which Beckman is offering to researchers where the recommendations outlined in the letter cannot be compiled with while continuing research programs.

NIH believes that, in view of the potential danger in secondary chemical explosions, Beckman has acted prudently and responsibly in the user notification for eliminating possible ultracentrifuge/rotor combinations. We strongly recommend that users of ultracentrifuges follow the instructions in the Beckman letter of June 22, 1984.

NIH grantee institutions may, within the normal prior approval policies, rebudget funds from other budget categories to assist in emergency replacement of equipment when such a step is required in order to continue the research activity. In the event that other supplemental funding is not available or the rebudgeting of existing funds is not possible, NIH awarding units may consider the authorization of administrative supplements in certain cases where they judge that absolutely essential replacements are required to carry out the NIH-supported research. NIH can not, however, guarantee supplemental financial assistance to replace existing equipment or parts.

Investigators with NIH contracts should reach the appropriate NIH project officer to discuss how to proceed on this issue if it is relevant to the contract. Only the NIH contracting officer, however, has the authority to authorize any major changes in the conduct or funding of the contract.

NIH also wishes to remind its grantees that the NIH is not legally responsible for accidents, illnesses or claims arising out of work undertaken with the aid of any grant or assistance award.

NOTICEWITHDRAWAL OF PROGRAM ANNOUNCEMENTS: DIAGNOSIS PROGRAM

P.T. 34; K.W. 1002014, 1200370, 1200640

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) hereby withdraws its program announcements entitled "Specific Immunoassays for Cancer Associated Isoenzymes" and "Non-invasive Approach for Detection of Lung Cancer," which appeared in the NIH Guide for Grants and Contracts, Vol. 12, No. 3, March 25, 1983. Please contact the NCI Diagnosis Program (Dr. Roger Aamodt, (301) 496-7147) if you have any questions concerning these announcements.

NOTICE

8TH ANNUAL NIH RESEARCH SAFETY SYMPOSIUM
CREATING A SAFE ENVIRONMENT FOR BIOMEDICAL
SUPPORT SERVICES PERSONNEL

January 10-11, 1985
Washington, D.C.

P.T. 42; K.W. 0701034

CONFERENCE DESCRIPTION:

The Division of Safety, National Institutes of Health (NIH) is pleased to announce its Eighth Annual NIH Research Safety Symposium. The symposium for this year will address the biological, chemical and radiological hazards facing auxiliary support personnel who work in biomedical research and hospital facilities. Specifically, the symposium is designed to:

- o Increase awareness about the wide range of safety and health problems facing maintenance and housekeeping personnel.
- o Provide a common theoretical framework from which to identify safety and health concerns so that practical solutions may be applied in various work environments.
- o Introduce training and information dissemination guidelines and strategies which can be adapted to various settings.
- o Promote dialogue and information exchange among conference participants.

Speakers with expertise as safety specialists, engineers, managers, and professional educators will address the four broad topic areas of this symposium:

- o Handling and disposal of biological, chemical and radiological agents.
- o Design of facilities (technical solutions to problems which minimize job-related risks).
- o Models of technical training approaches to handling job-related hazards.
- o Discussion of the managerial and technical responsibilities for protecting employees from hazards.

The general sessions are designed to provide a common basis from which to assess the technical, administrative and legal concerns facing administrative and support services personnel. The audience for the symposium will be managers of housekeeping, plant engineering, and support service departments, as well as professionals in the environmental health and safety arena.

GENERAL INFORMATION

- o Symposium Location: The symposium will be held at the Washington-Plaza Hotel, Massachusetts Avenue at Vermont, N.W., Washington, D.C. 20005. The telephone number is (202) 842-1300 or (800) 424-1140.
- o Accommodations: A block of rooms has been reserved at the Washington-Plaza Hotel for symposium participants. Room rates are \$60.00/night for a single and \$70.00/night for a double. Upon receipt of the registration form, a hotel reservation card will be mailed. In order to take advantage of symposium room rates and to be assured of a sleeping room, participants must return the hotel reservation form to the Washington-Plaza Hotel by December 20, 1984.
- o Registration: To register for the symposium, please return the registration form, which appears on the last page of this Guide, no later than DECEMBER 10, 1984 to:

Ms. Attrices Griffin
8th Annual NIH Research Safety Symposium
EXPAND ASSOCIATES, INC.
7923 Eastern Avenue - Suite 400
Silver Spring, Maryland 20910

There is no registration fee for the symposium. (Registration is limited to the first 300 persons.)

- o Luncheon: A luncheon for symposium participants will be held on January 10, 1985. Please indicate on the reservation form if you plan to attend. The cost of the luncheon is \$8.00 per person.
- o Continuing Education Units (CEU's): will be provided to members and non-members of the Environmental Management Association (EMA). For additional information, contact:

Harold C. Rowe
President, EMA
1019 Highland Avenue
Largo, Florida 33540

NOTICECHANGE OF POLICIES RELATING TO APPLICATIONS FOR PROGRAM PROJECT GRANTS ASSIGNED TO NIADDK

P.T. 34; K.W. 1200180, 1014002

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Program project grants provide support for broadly based multidisciplinary research programs each having well defined research objectives and employing the coordinated efforts of a number of individual project leaders. The typical program project consists of several interrelated projects and one or more supporting resources (core components).

The NIADDK has conducted a review of the current use of this mechanism in regard to its most effective utilization by NIADDK grantees. As a result, two changes in the guidelines for the program project mechanism have been made.

I. MAXIMUM REQUESTED BUDGETS

New program project applications submitted on or after February 1, 1985 and assigned to the NIADDK will be subjected to the following restriction: Requested budgets should not total more than \$1 million per year in direct costs when averaged over the requested project period. In cases where exceptional circumstances make this limitation inappropriate, applicants should consult with NIADDK staff well in advance of the anticipated submission date to permit careful fiscal and programmatic review.

Competing continuation applications will be subject to the following provisions:

- A. Program Projects currently funded by NIADDK with recommended budgets of \$1 million or more per year will be handled as follows:
 1. Competing applications submitted to renew projects scheduled to terminate before July 1, 1987 will not be subject to the \$1 million restriction.
 2. Competing applications submitted to renew projects scheduled to terminate on or after July 1, 1987 will be subject to the \$1 million restriction.
- B. Program projects currently funded by NIADDK with recommended budgets of less than \$1 million per year will be subject to the new maximum for competitive renewal applications submitted on or after February 1, 1985.

II. CHANGE IN REVIEW PROCEDURES

Currently, program project applications assigned to NIADDK undergo an initial review but separate numerical priority scores are not given to each component project. Initial Review Groups (IRG) may assign priority scores to projects recommended for approval and to applications recommended for approval. Priority scores for projects will be reported as advisory information in Summary Statements together with the review groups' perception of the relationship of each component project to the overall program objectives. Core components will not receive priority scores. It is expected that this change of review procedure will be helpful to the Institute in making decisions regarding the levels of funding to be awarded to program project applications.

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT GRANT APPLICATIONS FOR FISCAL YEAR 1985

P.T. 34; K.W. 1200280, 0404000

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: January 1, 1985

I. BACKGROUND

The Biomedical Research Support Grant (BRSG) Program is specifically designed to provide funds on a continuing basis to eligible institutions heavily engaged in health-related research to strengthen their programs by allowing flexibility available to the institutions to meet emerging opportunities in research; to explore new and unorthodox ideas; and to use these research funds in ways and for purposes which they (the institutions), in their judgment, feel would contribute effectively to the furtherance of their research program.

II. ELIGIBILITY

Awards are made to non-profit institutions, not directly to individual investigators. Health professional schools, other academic institutions, hospitals, state and municipal health agencies, and research organizations may apply if the institution received a minimum of three allowable PHS biomedical or health-related behavioral research grants, totaling \$200,000 (including direct and indirect costs), awarded during FY 1984 (October 1, 1983 through September 30, 1984). Federal institutions and institutions located in a foreign country are not eligible.

NOTE: Other academic includes, as a single eligible component, all other schools, departments, colleges and free-standing institutes of the institution except the health professional schools.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.337, Biomedical Research Support. Grants will be awarded under the authority of the Public Health Service Act, Section 301 (a)(3); Public Law 86-798, (42 USC 241) and administered under PHS grant policies and Federal Regulations 45 CFR Part 74 and the Biomedical Research Support Grant Information Statement and Administrative Guidelines. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

III. AWARD CONDITIONS

The BRSG award is for one year and must be renewed annually. The start date is April 1. It is estimated that approximately 556 BRSG awards will be made in FY 1985.

The amount of each BRSG award is based upon a formula that is applied to the total of direct and indirect costs awarded for allowable PHS research grants.

IV. METHOD OF APPLYING

BRSG application kits (Form NIH-147-1) will be mailed on or about November 26 to institutions that, according to NIH records, are eligible to apply for a BRSG.

Completed BRSG applications must be received by January 1, 1985.

If an institution believes that it is eligible and has not received an application kit by December 5, call:

Mrs. Gilda Polletto
Grants Management Specialist

ANNOUNCEMENT

AVAILABILITY OF SENIOR INTERNATIONAL FELLOWSHIPS FOR 1984-85

P.T. 22, 48; K.W. 1200170, 1200270, 1200180

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

Application Receipt Date: January 15, 1985

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) announces the availability of senior postdoctoral fellowships to outstanding U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of ideas and information in the biomedical, behavioral and health sciences. The types of activity that are supported by this program include collaboration in health studies, basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. This program does not provide support for brief observational visits, attendance at scientific meetings, attendance in formal training courses, independent research projects, or full-time clinical, technical or teaching services.

I. ELIGIBILITY REQUIREMENTS

Applicants must meet the following requirements.

- o Be a U.S. citizen or permanent U.S. resident.
- o Hold a doctoral degree in one of the biomedical, behavioral or health sciences.
- o Have five years or more postdoctoral experience.
- o Have professional experience in one of the health, biomedical or behavioral sciences for at least two of the last four years.
- o Hold a full-time appointment on the staff of a U.S. not-for-profit institution
- o Be nominated by the dean or appropriate U.S. institutional official.
- o Be invited by a not-for-profit foreign institution.
- o Not be a previous recipient of a Senior International Fellowship.

II. APPLICATION AND SELECTION

The next receipt date for Senior International Fellowship applications is January 15, 1985. All applications are reviewed for scientific merit by the National Institutes of Health. Fellowship awards are made for periods of three to twelve

months. A fellowship must be activated within one year after receiving the Notice of Award and the starting date of the fellowship is set by mutual agreement between the fellow and the collaborator at the foreign host institution. Prospective applicants for the Senior International Fellowship Program may obtain information brochures from FIC. Fellowship applications will be available from the FIC between October 15, 1984 and January 6, 1985 and may be requested only by the dean or equivalent institutional official. Information and fellowship applications are available from:

Senior International Fellowship Program
International Research and Awards Branch
Fogarty International Center
Building 38A - Rm 615
National Institutes of Health
Bethesda, Maryland 20205

For an expeditious reply, please send a self-addressed label with your request to the above address.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-NS-01

SENATOR JACOB JAVITS CENTERS OF EXCELLENCE IN NEUROSCIENCE

P.T. 34; K.W. 1200875, 1200870, 1002030, 0701007, 1200180

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application Receipt Date: January 15, 1985

I. PROGRAM OBJECTIVES AND SCOPE

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) announces the availability of a limited number of awards for Senator Jacob Javits Centers of Excellence in Neuroscience. These awards have been proposed by the Congress to honor former Senator Jacob Javits of New York. In the words of the Congressional proposal: "The centers shall be dedicated to finding the cause, prevention, and cure for neurological diseases and shall be designed so that multidisciplinary teams of the most capable scientists would address fundamental biological issues of nervous system structure and function."

The NINCDS plans to implement this proposal through its program project (P01) mechanism, by supporting the research of small groups of investigators on the forefront of an area of the neurological or communicative sciences which shows promise of a major contribution to the understanding of the nervous system and its disorders. The groups of investigators should consist of independent, highly-qualified research workers who have through their individual or collective efforts demonstrated a high potential for scientific achievement. The merit of applications will be judged on the credentials and past research accomplishments of the investigators, the significance of the area of research proposed, the interrelationships of the scientists in the group, and a general description of the intended approaches. A demonstration of the significance and likelihood of success of the proposed approach in relation to long-term research objectives will be important. Planned time commitments of each of the senior investigators to the proposed research effort should be described.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853, Stroke, Nervous System Trauma. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. ELIGIBILITY AND REVIEW

For profit and non-profit organizations or institutions in the United States are eligible to apply. Applications will be reviewed by an initial scientific merit review group specifically constituted for this RFA. Secondary review will be performed by the National Advisory Neurological and Communicative Disorders and Stroke Council; grants can be awarded only upon a recommendation of approval by the National Advisory Council.

III. MECHANISM OF SUPPORT

These centers of excellence will be supported through the program project (P01) mechanism. Although this program is provided for in the financial plans of the NINCDS, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose. The Institute expects to make up to five awards in amounts up to \$750,000 per year direct costs. Awards will be made for periods of five years, and will be issued no later than September 30, 1985.

IV. APPLICATION

Applications should be submitted on form PHS 398 according to the instructions provided with the form and according to supplemental guidelines for this program, available from NINCDS (see below). Applicants should not attempt to respond to this RFA without acquiring and following these supplemental guidelines.

Applicants will be required to document past performance and potential for future contributions. These applications will differ from the usual program project applications in that individual sub-projects will not have to be described in as much detail. Instead, the concept(s) to be explored should be described in detail, as well as the background and progress to date and the general research direction(s) to be taken by each senior investigator and his/her colleagues during the period of the grant award. Only one consolidated or composite budget request will be required. Direct costs for up to \$750,000 in each of five years may be requested. The usual budget categories contained in form PHS 398 will be applicable. The receipt date for applications is January 15, 1985.

The original and six copies of the application should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

V. LETTER OF INTENT AND INQUIRIES

In order to assist the NINCDS in making plans for the scientific merit review of applications, all applicants are asked to submit a letter of intent, describing briefly the area of research for which support will be requested, and the names of the principal investigators who will be responsible for the research. The letters should be mailed to Dr. John C. Dalton (see address below) so as to be received in NINCDS by December 1, 1984.

For further information concerning this program, and for detailed supplementary application guidelines (which must be followed if an acceptable application is to be submitted) contact:

Dr. John C. Dalton
Director, Extramural Activities Program
National Institute of Neurological and
Communicative Disorders and Stroke
Federal Building - Room 1016
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9248.

ANNOUNCEMENT

RESEARCH GRANTS ON BASIC MECHANISMS OF THE EPILEPSIES

P.T. 34; K.W. 1200330, 1002030, 1200180, 1200900, 1200820, 1002008

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application Receipt Dates: March 1, July 1, and November 1

I. INTRODUCTION

The Epilepsy Branch, Convulsive, Developmental, and Neuromuscular Disorder Program, National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) encourages the submission of research project grant applications (R01) related to the basic mechanisms of the epilepsies.

II. BACKGROUND

Over the last decade, advances in the neurosciences have seen the development of new concepts in cell recognition, intracellular communication, and cell to cell information transfer. In December 1983, an international symposium on Basic Mechanisms of the Epilepsies provided a critical, definitive statement of current knowledge, and was intended to foster the application of the advances in cellular and molecular neurosciences to the understanding of seizure generation, spread and arrest. Such understanding is fundamental to more effective prevention, diagnosis, and treatment of seizures.

At the international symposium, a number of cogent areas which could profit from immediate research, including problems requiring application of new technologies to epilepsy research, were identified. The NINCDS seeks to encourage cross-communication among diverse scientific disciplines so that the potential of all of the relevant neurosciences can be brought to bear on the basic mechanisms of the epilepsies.

This program is described in the Catalog of Federal Domestic Assistance No. 13.854, Biological Basis Research, NINCDS. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

III. RESEARCH GOALS

The goals of this research program are to obtain information about basic mechanisms in the production of seizures. Examples of some of the new concepts in neurosciences are given below, but applications are not limited to these.

Recent advances have occurred specifically in the areas of molecular genetics, where the application of recombinant DNA technologies to biological problems are revealing the sequence complexities of brain RNA transcriptional control and the processing of secretory products. In molecular neurosciences, the isolation and subdivision of acetylcholine, opiate, glutamate, GABA, and benzodiazepine receptors have provided a solid basis for increased understanding of transducer mechanisms by which target cells are activated. The regulation of these receptors by neurotransmitters, neuromodulators, and ligands may be of major importance in epilepsy. Selective purification of Na⁺, K⁺ ATPase and Ca²⁺, Mg²⁺ ATPase and reconstitution experiments of the alpha, beta, and gamma subunits of Na⁺, K⁺ ATPase, including monoclonal antibodies to the alpha subunit, are now available and are being tested for functional abnormalities in epileptogenic states.

In cellular physiology, neuron nets and electrical coupling have assumed important roles as neuronal ensembles responsible for higher cortical functions. Non-activating calcium conductances, followed by both voltage dependent and calcium dependent potassium currents in dendritic elements, and inactivating and non-activating voltage dependent sodium, potassium, and calcium conductances in neuronal soma are now being complemented by molecular studies. A variety of new single microelectrode methods are available to define the contributions of electronic and synaptic transmission, transitional characteristics of open and closed channels, and the ionic events in the paroxysmal depolarization shifts.

IV. MECHANISM OF SUPPORT

Support for this program will be through the traditional research grant-in-aid. Successful applicants will direct and carry out the individual research projects.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS 398 according to instructions contained in the application kit. Application kits are available from most institutional business offices or may be obtained from the Division of Research Grants at the address given below.

Check "yes" in item two on the face sheet of the application and type **"Grants Related to the Basic Mechanisms of the Epilepsies"** in the space provided.

Applications must be responsive to the program announcement and the goals of NINCDS. They will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants. A second level of review will be made by the National Advisory Neurological and Communicative Disorders and Stroke Council.

Deadlines for the receipt of applications are: November 1, March 1, and July 1.

The original and six copies of the application should be mailed to the following address:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland - 20205

An information copy of the application may be sent to the address below. Also, for further information applicants may contact:

James J. Cereghino, M.D.
National Institutes Health
NINCDS, CDNDP, EB
Federal Building - Room 114
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1917

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-AI-01

PROGRAM PROJECTS ON MECHANISMS OF IMMUNOLOGIC DISEASES

P.T. 34; K.W. 1200610, 1200640, 1200630, 1002015, 1003002, 1002034, 0701038

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: June 15, 1985

I. BACKGROUND INFORMATION

The Immunopathology Branch of the Immunology, Allergic and Immunologic Diseases Program (IAIDP) of the National Institute of Allergy and Infectious Diseases (NIAID) is concerned with cellular and molecular mechanisms of immunologic diseases. This request for applications (RFA) is intended to encourage the development of applications from collaborative basic science and clinical investigative groups, and to coordinate the submission of new and renewal program project applications providing equitable opportunity for both to compete for funds currently available for existing programmatic activities concerned with the study of mechanisms of immunologic diseases. Eight such program projects are currently funded and support for four are scheduled to conclude in 1986.

II. RESEARCH GOALS AND SCOPE

Realizing that immunologic diseases and inflammatory disorders constitute major areas of endeavor of the Immunopathology Branch, the goals of these program projects are aimed at understanding the underlying mechanisms of disease and the development of diagnostic measures and approaches to effective prevention, control, and treatment of a wide variety of immunologic disorders. The scope of these program projects is intended to include studies of all aspects of immunologic responses aimed at defining etiologic factors and pathogenetic mechanisms.

Research approaches in this area include clinical immunology studies of acquired and inherited diseases associated with dysfunctions of the immune system and immunopathology studies of the genetics, cytology, biochemistry, physiology, and pharmacology of the immune system and its disorders.

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulation 42 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

III. MECHANISM OF SUPPORT

Program project grants are awarded to an institution on behalf of a program director for support of a broadly based, multidisciplinary, long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators, whose members conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain core resources shared by individuals in a program where the sharing facilitates the total research effort. Each component project supported under a program project grant is expected to contribute to and be directly related to a common theme; the projects should demonstrate an essential element of unity and interdependence.

IV. STAFF CONTACT

A more detailed RFA may be obtained from:

Robert A. Goldstein, M.D., Ph.D.
Chief, Immunopathology Branch, IAIDP
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

Prospective applicants are encouraged to submit a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The Institute requests such letters by March 15, 1985, for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding. It will not enter into the review of any application subsequently submitted and is not a requirement for application. Letters of intent and inquiries should be directed to Dr. Goldstein at the address shown above.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

85-CA-01

COOPERATIVE GROUP FOR STUDIES ON MUTAGENS IN HUMAN FOODS

P.T. 34; K.W. 1002014, 1002028, 0202022, 1003008

NATIONAL CANCER INSTITUTE

Application Receipt Date: January 15, 1985

The Division of Cancer Etiology (DCE) of the National Cancer Institute (NCI) invites cooperative agreement applications from groups of interested investigators for basic studies intended to provide insights and approaches to an understanding of the possible role of food mutagens in human cancer causation.

BACKGROUND

Concern over the presence of mutagens in human foods is part of a large and growing interest in the role of diet in human cancer causation and in the possible inhibition of cancer by dietary means. In this contest, the relevance of dietary mutagens derives from their genotoxic effects which could lead to cancer induction. Concern over dietary mutagens gains further emphasis from the widespread occurrence of mutagens in human foods. Apart from the well-publicized association of mutagens with charcoal-broiled steak, mutagen formation has been reported to occur upon the boiling of beef stock, the broiling of hamburgers at a relatively modest surface temperature, the frying of potatoes, and the toasting of bread. Mutagens have also been found to be present in many vegetables, in alcoholic beverages, spices, coffee, and tea. Various contaminants may also constitute a source of mutagens present in human foods. According to one estimate, the foods and beverages ingested by an individual in the course of a single day might contain 1-2 grams of mutagens.

OBJECTIVES AND SCOPE

The purpose of this RFA is to accelerate the development of additional understanding relative to the possible role, fate, and cancer relevance of known dietary mutagens commonly present in human foods. Applications submitted in response to this RFA should be responsive to one or more of the items selected from any one or from a combination of the following categories:

- A. In depth, basic studies on a small number of mutagens selected from among those which are known to occur naturally in human foods, those found in human feces, and those human dietary mutagens the formation of which is associated with the processing and preparation of food; compounds of particular interest include, but are not limited to, the following six classes:
 1. Heteroaromatic amines of the carboline and imidoquinoline types.

2. Hydroxylated flavonoids.
 3. Carbonyl compounds such as acrolein, malonaldehyde and methylglyoxal.
 4. Fecapentaenes.
 5. Endogenous N-nitroso compounds.
 6. Aromatic hydrocarbons.
- B Development of analytical procedures for the quantitation of the foregoing mutagens in foods and for the quantitation of them and their respective metabolic products present in blood, body fluids and tissues, and feces.
- A. In vitro and in vivo studies relative to the absorption, metabolism, and possible carcinogenicity of selected compounds such as quercetin and the human fecapentaenes. However, full scale animal bioassays will not be supported through this announcement.

MECHANISM OF SUPPORT

This announcement seeks to make at least one award for a group funding arrangement that permits a combination of available research expertise from diverse institutions (academic, not-for-profit, and industrial) and the facilitating resources of the NCI. Awards will be made as cooperative agreements. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. Units, in which these research talents and resources are combined, are termed "Cooperative Groups." The composition of a Cooperative group is envisioned as requiring a group director, an NCI coordinator, and program leaders in four broad scientific disciplines: biology, chemistry, biochemistry, and toxicology. Alternative scientific disciplines may be proposed if they are essential to the scientific objectives and experimental approaches planned. As more completely described in the RFA which is available, the recipients will have primary responsibility for the development and conduct of the research. The role of the NCI coordinator will be that of a facilitator and not that of a director. The initial project period proposed should not exceed four years.

INQUIRIES

Copies of the complete RFA and additional information may be obtained from:

Chief, Chemical and Physical
Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9B01
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-5471

To insure their review, applications must be received by January 15, 1985.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

85-CA-02

INTER-INSTITUTIONAL NETWORK FOR AUTOMATED FLOW CYTOMETRY
RESEARCH IN THE DIAGNOSIS AND TREATMENT OF URINARY BLADDER CANCER

P.T. 34; K.W. 1200370, 1201275, 1004019, 0603000

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: November 16, 1984
Application Receipt Date: January 11, 1985

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites cooperative agreement applications for support of participation in an inter-institutional Flow Cytometry Network for research in urinary bladder cancer. This Announcement indicates the availability of a Request for Applications (RFA). Copies of the RFA must be requested in writing with the RFA number, 85-CA-02, indicated.

The major goal of this RFA effort is to encourage rapid development of a state-of-the-art Flow Cytometry Network to serve the diagnostic and treatment needs of bladder cancer patients. The proposed Network of collaborating laboratories will evolve optimum methods for identifying bladder cancer through steps of technique modification and refinement. Flow cytometry will be evaluated for detecting tumor recurrence in bladder cancer patients who are receiving chemical, radiation or immunotherapy, and for monitoring symptomatic patients and high-risk populations.

The principal investigators in the Network will have primary responsibility for planning, directing and evaluating research in conjunction with an active participation by the DCPC program staff throughout the course of the study. DCPC staff will periodically evaluate research priorities and review progress to ensure that the Network conforms to the objectives and conditions of the award.

The intent of the RFA is to initiate inter-institutional clinical studies of the urinary bladder among flow cytometry laboratories which are already contributing to cancer research. The required technical expertise, facilities and resources should already exist in an applicant institution which responds to the RFA.

An applicant institution may apply for a period of support of up to three years under the RFA. A maximum of five awards will be made. The specific amount to be awarded will depend on the availability of funds. Such awards will support only inter-institutional aspects of the research program. Core support for bladder cancer flow cytometry at the applicant institution must be fully funded through alternative mechanisms. This type of RFA is used when the NCI--with concurrence of a Board of Scientific Counselors--wishes to stimulate investigator interest, proposes to assist in research planning, and intends to monitor investigator progress in an important and opportune area of research. Applicants should be aware that in the case of this Announcement and RFA solicitation, the NCI has funds committed to this specific program need.

A potential applicant institution is encouraged to submit a letter of intent and to consult with NCI staff before submitting an application in response to the RFA. The letter of intent is due on November 16, 1984. Information in the letter should indicate how capably the applicant institution is able to respond to the requirements of the RFA. All such letters will be evaluated and answered by NCI staff.

Institutions within the United States may apply. Applications must address all requirements in the RFA. Form PHS-398 (revised 5/82) should be used, which is the application form for the traditional research project grant. It is available in the business and grant-contract offices of most academic and research institutions, or from the Division of Research Grants (DRG), National Institutes of Health (NIH) Bethesda, Maryland 20205.

The original and six copies of the application should be delivered to the DRG no later than January 11, 1985.

Neither this Announcement nor the RFA commits the Government to award a cooperative agreement.

Requests for copies of the complete RFA and inquiries related to further information, application development or letter of intent should be sent to:

William E. Straile, Ph.D.
Cancer Centers Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 727
8300 Colesville Road
Bethesda, Maryland 20205

Telephone: (301) 427-8818

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-03

CYTOGENETICS AND PREDISPOSITION TO CANCER

P.T. 34; K.W. 1002014, 1002015, 1002019, 1201330

NATIONAL CANCER INSTITUTE

Application Receipt Date: March 15, 1985

The Division of Cancer Biology and Diagnosis (DCBD) of the National Cancer Institute (NCI), is inviting grant applications from interested investigators to determine whether certain sites on chromosomes can be identified as predisposing factors in human cancer. Recent research in cytogenetics has indicated that there may be significant correlations between certain nonrandom chromosomal aberrations and particular types of cancer. Improved techniques for eliciting and examining these alterations in human chromosomes have contributed to the development of a small but growing body of data which supports the potential importance of cytogenetic analysis to the early detection, diagnosis and prognosis of cancer. Considerably more data are necessary in order to confirm the importance of these observations.

This type of solicitation (the RFA) is being used to encourage investigator initiated research projects studying nonrandom identifiable chromosomal sites and to focus this research on the relationship of these sites to cancer. This is an area of special importance to the National Cancer Program. Support for such awards is through the traditional NIH grant-in-aid and is governed by the policies applicable to such grants. All applications in response to the RFA will be reviewed by an appropriate peer review group of NIH.

The present RFA announcement is for a single competition with a specified deadline of March 15, 1985 for receipt of applications.

This program is described in the Catalog of Federal Domestic Assistance No. 13.394, Cancer Detection and Diagnosis Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

I. RESEARCH GOALS AND SCOPE

Significant progress has been made in the ability to elicit and identify fragile sites. In order to maximize the opportunities to identify additional nonrandom chromosomal sites which might be significant in cancer, more research must be done to improve the techniques for eliciting such sites and for fine structure analysis of chromosomes. The hereditary pattern of new sites must be established. Studies must be designed to determine whether the known sites and newly discovered ones act as predisposing factors in human cancer. The purpose of this RFA is to encourage applications directed toward development of new techniques and toward testing the hypothesis of the relationship between fragile sites and other identifiable nonrandom sites and cancer. It is hoped that suitable collaborations will be developed between clinicians with access to appropriate patient populations and basic scientists involved in cytogenetic research.

II. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional NIH grant-in-aid. Applicants will plan and execute their own programs. Approximately \$625,000 will be set aside to specifically fund applications which are submitted in response to the RFA. It is anticipated that four to five applications can be funded. These applications will not compete for funding within the general pool of dollars available for other investigator-initiated research proposals. However, all applications received will be evaluated by the rigorous standards of Study Section review. The expected starting date is December 1, 1985. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is contingent upon availability of funds appropriated for Fiscal Year 1986. Only applications of sufficiently high scientific merit will be funded.

III. INQUIRIES

A copy of the complete RFA describing the research goals and scope, the review criteria and the method of applying can be obtained by contacting:

Sheila E. Taube, Ph.D.
Chief, Biochemical Diagnosis Section
Division of Cancer Biology and Diagnosis
National Cancer Institute
Westwood Building - Room 10A15
Bethesda, Maryland 20205

Inquiries concerning this announcement are encouraged and should be directed to Dr. Sheila E. Taube at the above address (Phone 301-496-7147). The program would appreciate the opportunity to clarify any issues or questions from potential applicants.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS:

85-CA-04

CONTINUING CARE RESEARCH: IDENTIFYING AND REDUCING OBSTACLES FOR CANCER PATIENTS

P.T. 34; K.W. 1002014, 0701037, 0701029, 0403004

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: November 4, 1984

Application Receipt Date: January 8, 1985

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for research projects which address the various concrete problems that confront cancer patients and/or their families.

I. BACKGROUND

Concrete problems are defined as those administrative and functional issues that confound or limit the ability of a cancer patient or his family to cope with the treatment and the consequences of cancer. They emerge from the interaction of the cancer patient and their families with the cancer care system. Resolution of such problems may involve changes in personal skills or knowledge, or changes in institutional and community services available. However, the primary focus of this request for applications is not unmet psychological needs of cancer patients and their families; such needs are less clearly linked to the system of cancer care.

II. OBJECTIVES AND SCOPE

This initiative encourages studies that seek ways to facilitate the resolution of concrete problems. As a first step, investigators will establish the incidence and prevalence of concrete problems found in their cancer care setting. They will estimate the extent and efficacy with which available resources or services have solved these concrete problems. Following an analysis of these data, a second step will involve implementation of a program(s) aimed at resolving the obstacles that contribute to the creation or maintenance of such concrete problems. The awardees will individually prioritize these needs, and design specific interventions based on local needs or demands and available resources and personnel. The proposed research effort will be divided into the following stages:

- A. Descriptive Studies: Perform prospective surveys, using a common instrument and set of definitions, to determine the incidence and prevalence of resolved and unresolved concrete problems. The description should include information related to site and stage of disease and functional status of the

patient. Characterize the efficiency and effectiveness of existing mechanisms for the resolution of concrete problems. Develop a predictive model for practical interventions.

- B. Implementation Program: Implement a program consisting of evaluable interventions aimed at maximizing resolution of concrete problems. Evaluate the predictive model and the efficacy of the interventions.

III. MECHANISM OF SUPPORT

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. The terms of award will detail the Government involvement and will specify the level of NCI program assistance and cooperation. Awards will be made for a period of four years. NCI anticipates making six awards as a result of this request. A total of \$300,000 has been set aside to fund the direct costs of the awards for the initial year.

IV. STAFF CONTACT

Copies of the complete RFA and additional information may be obtained from:

Mrs. Wilma H. Dunlap
Community Outreach and Rehabilitation Branch
Centers and Community Oncology Program
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 7A05
Bethesda, Maryland 20205

Telephone: (301) 427-8708

ANNOUNCEMENT

RESEARCH ON BIOLOGICAL RESPONSE MODIFIERS

P.T. 34; K.W. 1200130, 1200820, 1200520, 1200244, 1201320, 0602000

NATIONAL CANCER INSTITUTE

Application Receipt Dates: March 1, July 1, November 1

The National Cancer Institute (NCI), Division of Cancer Treatment (DCT) desires to expand its support for several areas of research dealing with biological response modifiers related to clinical treatment. Five areas of special interest to the Institute are described below. Interested applicants are encouraged to contact the NCI staff members listed for additional information.

In making this program announcement it is not the intent of the NCI to make or imply any delimitation related to the biological response modifier research, but rather to stimulate investigator initiated research in biological response modifiers.

Applications in response to this announcement will be reviewed in accordance with the usual National Institutes of Health (NIH) peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

DETERMINATION OF THE THERAPEUTIC USEFULNESS OF PURIFIED CYTOKINES
AND ANTI-CYTOKINE MONOCLONAL ANTIBODIES IN CANCER MODELS

The NCI, DTC desires to expand its support of research on cytokines (lymphokines, monokines, growth factors, etc.) and in determining the potential for using these factors in the treatment of cancer. The Biological Response Modifiers Program is seeking applications for research grants concerned with the modes of action of purified cytokines in ways that will be relevant to determination of therapeutic potential through direct effects on certain types of malignant cells or on supportive tissue of tumors. Methods of regulating or manipulating the specific cytokine levels through utilization of purified cytokines and/or utilization of anti-cytokine monoclonal antibodies are of interest. Work with in vivo animal models would be particularly relevant.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

For further information, investigators are encouraged to contact:

Dr. Gary B. Thurman
 Program Director for Molecular Immunology
 Biological Resources Branch
 Biological Response Modifiers Program
 Division of Cancer Treatment
 National Cancer Institute
 Frederick Cancer Research Facility
 Building 426 - Room 1
 Frederick, Maryland 21701

Telephone: (301) 695-1098

USE OF GROWTH FACTORS, MATURATION FACTORS AND ANTI-GROWTH FACTORS IN ANIMAL TUMOR MODELS

The NCI, DCT, desires to expand its support of clinical treatment research. The program is seeking applications for research grants concerned with the therapeutic effects of growth factors, maturation factors, and monoclonal antibody to growth factors on the growth and metastasis of cancer in animal tumor models.

For further information, investigators are encouraged to contact:

Dr. Cedric W. Long, Acting Chief
 Biological Resources Branch
 Biological Response Modifiers Program
 Division of Cancer Treatment
 National Cancer Institute
 Frederick Cancer Research Facility
 Building 426 - Room 1
 Frederick, Maryland 21701

Telephone: (301) 695-1098

USE OF TUMOR ASSOCIATED ANTIGENS AS IMMUNOGENS

The program is seeking applications for research grants concerned with the development of methods of immunization that evoke effective in vivo anti-tumor immunity using purified tumor associated antigens as immunogens. Isolation of tumor associated antigens is now possible using monoclonal antibodies. There is considerable uncertainty, however, how best to administer purified antigens in vivo to evoke effective anti-tumor immunity. Certain antigens may facilitate and others may inhibit tumor growth and metastases. The proposed studies should investigate this issue in both normal and tumor bearing animals using purified antigens as therapeutic agents. Preference will be given to non-viral tumor associated antigens on recently derived spontaneous or chemically induced fully syngeneic tumors although consideration will be given to viral coded tumor

antigens and even normal cell surface alloantigens as model antigens. The use of various immunization schedules and adjuvants in therapy models with detailed monitoring of the host cellular and immune responses will be required. These studies must be directed toward optimizing the therapeutic effects of these antigens in vivo as demonstrated by protection studies against subsequent tumor growth. Proposals to investigate monoclonal antibody purified tumor associated antigens as therapeutic reagents in many may also be submitted. As in the animal models, homogenous preparations of high purity are preferred for these investigations. End points may be assessed by in vitro or by in vivo therapeutic effects.

For further information, investigators are encouraged to contact Dr. Cedric W. Long at the address given above.

DEVELOPMENT OF CELL LINES PRODUCING LYMPHOKINES AND CYTOKINES

The program is seeking meritorious grant applications for research grants concerned with the development of cell lines and the development of methods to isolate, purify and characterize the therapeutic potential of the various products of these cell lines in appropriate test systems. These products may have a potential long-term usefulness in the treatment of cancer and/or in the alteration of biological responses in the course of cancer.

For further information, investigators are encouraged to contact Dr. Cedric W. Long at the address given above.

DEVELOPMENT OF GENETICALLY ENGINEERED CELL PRODUCTS

The program is seeking applications for research grants concerned with the development of genetically engineered cell products for therapeutic application as biological response modifiers. This announcement will support diverse approaches into the use of genetic engineering to transpose genes coding for biological response modifiers such as interferons, lymphokines, growth factors and other gene products into microbial organisms for a large scale production, isolation, purification and characterization of these factors for therapeutic application as biological response modifiers.

For further information, investigators are encouraged to contact Dr. Cedric W. Long at the address given above.

DEADLINE

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates are: March 1, July 1, November 1.

METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the grants and contracts business office at most academic and research institutions or from the Division of Research Grants (DRG), NIH. In space #2 on the first page of this form, indicate the title of the Program Announcement.

Additionally, a brief covering letter should accompany the application indicating it is being submitted in response to this program announcement. All applications will be received by the NIH's Division of Research Grants (DRG) and assigned to awarding organizations based on current guidelines used by the DRG. All PHS and NIH grant policies governing regular research project grants, including cost-sharing, will apply to applications received in response to this Program Announcement. Non-profit organizations and institutions, governments and their agencies, for-profit organizations and individuals are eligible to apply. The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In order to alert the DCT to the submission of applications with primary thrust directed to biological response modifiers research, a copy of the covering letter should be sent under separate cover to Dr. Thurman or Dr. Long, as appropriate, at the addresses given above.

ANNOUNCEMENTMEDICAL IMAGING FOR DIAGNOSIS AND TREATMENT OF CANCER

P.T. 34; K.W. 1200380, 1200370, 1002014, 1200280, 0607024, 0603000

NATIONAL CANCER INSTITUTE

Application Receipt Dates: March 1, July 1, November 1

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) supports a variety of research programs in the area of medical imaging for the diagnosis and treatment of cancer. The present program announcement is to encourage the submission of scientifically meritorious applications in the areas described below.

DEVELOPMENT OF NEW AND IMPROVED CONTRAST MEDIA

The pressing need for effective low cost and less toxic contrast agents for conventional and ultrasound diagnostic imaging, as well as for new modalities such as magnetic resonance imaging (MRI) mandated this initiative. This announcement is to emphasize the continuing interest of the Diagnostic Imaging Research Branch (DIRB), RRP, DCT, NCI in innovative research in contrast media (CM) and encourage the submission of applications leading to the advancement and improvement of the state-of-the-art in this important area of cancer detection.

There is an unfilled need for radiographic contrast media that will provide improved delineation of organs and disease processes. The present agents either do not work well or have limitations of use because of toxicity. The recommendation for development of these agents grows out of needs expressed by the report of the "Task Force on Imaging" which was developed in 1983 and published in the Investigative Radiology Supplement of May-June 1984. Special areas of interest specifically identified are:

1. Development of less expensive nonionic substances, MRI general media, and media for ultrasound.
2. Development of paramagnetic contrast agents for MRI.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

3. The brain, kidney, and spinal cord to a greater degree than other organs are likely to be damaged by contrast agents. Better and safer CM are needed for angiography, CT, myelography, and cisternography.
4. Research in the pathogenesis of life-threatening adverse reactions, anaphylaxis occurring with current and new CM, and to study predictive tests and preventive measures.
5. Clinical trials for comparative cost, efficacy, and safety of new and current media.
6. Increase diagnostic efficacy and decrease morbidity and mortality of imaging examination.
7. Develop new tissue and lesion specific media.

Other areas of research in contrast media inadvertently omitted in this announcement would be appropriate to this program.

For further information contact:

Dr. Matti Al-Aish
Program Director
Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
National Institutes of Health
Landow Building - Room 8C09
Bethesda, Maryland 20814

Telephone: (301) 496-9531

RESEARCH ON 99m TECHNETIUM AND/OR 123 IODINE LABELED
RADIOPHARMACEUTICALS AND ASSOCIATED TOMOGRAPHIC IMAGING SYSTEMS

NCI also encourages the submission of scientifically sound and meritorious applications in the areas of single photon labeled radiopharmaceuticals and tomographic imaging systems (SPECT) that utilize these agents.

Recent developments in other areas of diagnostic imaging including ultrasound, positron emission tomography, and magnetic resonance imaging have reduced attention to radiopharmaceutical and associated instrumentation research. This announcement emphasizes the interest and support of the RRP, NCI in innovative and significant investigation in these areas. It is intended that products of the investigations will be readily usable for diagnosis and treatment of cancer in most hospitals.

Nuclear Medicine procedures have the advantages of wide availability and relatively low cost for instruments and radiopharmaceuticals in the usual clinical settings. The procedures are cost effective for clinical use and research. The scope of this announcement encompasses investigations that will develop and improve all aspects of the title area including instrumentation, computer algorithms, and radiopharmaceutical development and testing.

A workshop held in Bethesda, Maryland, in 1984, identified the following specific areas of special interest for scientific and technological development; however, applications are not limited to these areas.

1. Better refinement and characterization of presently available SPECT systems.
2. The development of improved SPECT systems either based on new or novel technology.
3. Further technical development of gamma camera based SPECT systems including collimator design and gantry and/or detector refinement.
4. Development of integrated mathematical models of SPECT data collection and image reconstruction including attenuation, scatter, detector characteristics and uniformity, and image forming elements with the goals of improved spacial resolution and/or improved quantitation.
5. A study of the relationships between chemical structure and in vivo transport and metabolic disposition of potential biomedically useful 99m Technetium and/or 123 Iodine radiotracers as probes of physiologic processes.
6. Development and validation of 99m Technetium and/or 123 Iodine radiotracers for the study and/or detection of primary cancer, cancer metastasis, heart biochemistry (glucose or fat metabolism), heart blood flow, brain metabolism, brain blood flow, and/or other organ metabolism or blood flow.
7. Development of methods or procedures for evaluating possible toxicity of radiotracers developed under 5 and 6 above that will allow prompt dissemination of useful tracers into clinical medicine.

This list is not meant to be complete and applications on other topics or areas are welcomed.

For further information, contact Dr. Al-Aish at the address given above.

TISSUE CHARACTERIZATION BY ULTRASOUND AND BY X-RAY COMPUTED TOMOGRAPHY

An elaborate "Plan for Diagnostic Imaging Research," developed by a large Task Force of clinical and physical scientists in medical imaging, was recently published as a Supplement to the May/June 1984 issue of the journal "Investigative Radiology." This plan identifies for investigators a wide variety of clinical needs and potential scientific opportunities in diagnostic imaging research and should be examined for its descriptions of additional suitable topics for research of interest to NCI and other institutes of NIH.

This announcement invites grant applications for research studies and for development, initial evaluation, and/or application of new and improved techniques for noninvasive characterization of biological tissues by either of two imaging modalities: (A) ultrasound and (B) X-ray computed tomography (CT). These modalities are independent of each other and are selected simply for current emphasis. Responses to this announcement are typically expected to address only one or the other.

Tissue characterization in this context means the ability to specify qualitatively or quantitatively the physiological or pathological state of tissues or of their functions, or the identity of specific tissues, or the viscoelastic properties or other intrinsic parameters of tissues by use of information from these imaging modalities. Techniques which image flow or provide assessment of flow or perfusion, including the use of contrast media, may potentially contribute to tissue characterization.

A. Ultrasound

Although ultrasound imaging applications have proliferated in number and variety, additional electronic information is contained within the acquired signals from pulsed and continuous wave ultrasound imaging and flow equipment that has not been fully utilized. Examples of possible avenues for improvement include, but are not limited to, sophisticated signal processing of digitized radio-frequency signals; wider aperture and multiple transducer arrays to obtain correlatable signals from many angles; frequency diversity techniques; higher capacity, faster, and lower-priced computers; and novel methods for acquiring, processing, and displaying data.

Application areas for ultrasound tissue characterization include, for example, breast disease and neoplasms of abdominal organs (liver, pancreas, spleen, kidneys).

B. X-ray Computed Tomography

Few attempts have been made to achieve specific characterization of tissues from CT data and with limited success. Innovative ideas appear to be needed in methods for acquiring, processing, and displaying x-ray CT data. This area must be regarded as exploratory at the present time, but the millions of CT images taken weekly suggest the importance of making advances in the full use of these data. Application areas may include differential bone density measurement, tumor detection, and the characterization of musculoskeletal neoplasms.

For further information contact:

Mr. Roger S. Powell
Program Director
Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
National Institutes of Health
Landow Building - Room 8C-09
7910 Woodmont Avenue
Bethesda, Maryland 20814

Telephone: (301) 496-9531

ELIGIBILITY

Non-profit organizations and institutions, governments and their agencies, for-profit organizations, and individuals are eligible to apply.

REVIEW PROCEDURES AND CRITERIA

Applications should be submitted on form (PHS-398-Rev 5/82), which is available in the institution's collaborative research or business office; otherwise an application kit may be obtained from the Office of Grants Inquiries, Division of Research Grants (DRG) NIH. The original and six copies of the application should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Upon receipt of the applications, the Referral Office, DRG will assign each application to a specific NIH institute, in accordance with the usual referral guidelines, for possible funding and to a Study Section composed mostly of non-Federal scientific consultants for scientific and technical merit review. Subsequently, the applications assigned to NCI will be evaluated for program relevance by the National Cancer Advisory Board (NCAB). All applications recommended for approval will compete with other regular ROI approved grant applications for available funds. All PHS and NIH grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this program announcement.

The title of this announcement, "**Medical Imaging for Diagnosis and Treatment of Cancer,**" should be typed under item 2 on page 1 of the application and the "yes" should be checked to indicate a response to this announcement.

Application receipt dates are March 1, July 1, and November 1.

ANNOUNCEMENT

PREDICTION OF TUMOR RESPONSE TO RADIATION THERAPY

P.T. 34; K.W. 1201180, 1201275, 1002014

NATIONAL CANCER INSTITUTE

Application Receipt Dates: March 1, July 1, November 1

The Radiotherapy Development Branch of the Radiation Research Program, Division of Cancer Treatment (DCT), National Cancer Institute (NCI), is interested in supporting research in the area of predictive assays for tumor response to radiation therapy.

Radiation therapy has been an important treatment for human malignancies since the turn of the century. Despite advances in tumor localization and radiation therapy equipment and technique, there are a large number of localized malignancies that are not cured by proper application of radiation therapy. The response of a tumor to radiation therapy depends upon many factors intrinsic to the tumor cell itself as well as factors related to its local environment. There has been significant progress in recent years in developing techniques for analyzing the local environment and the intracellular environment itself.

Several intracellular parameters have been identified which may constitute either direct or indirect measurement of cellular radiosensitivity. DNA strand break and repair is such a parameter, as is the related process of potentially lethal damage repair. The micronucleus assay has also been developed and is based on the consideration that the micronucleus represents genetic material lost from the main genome of the cell and indicates therefore a loss of reproductive integrity. Correlations between micronucleus frequency and parameters of the clonogenic cell survival curve have been demonstrated both in vitro and in vivo. Other parameters that have been shown to be useful, either singly or in combination, included DNA content, ploidy, number of S-phased cells, and sulphhydryl content.

Extracellular environmental factors influencing radiosensitivity include oxygen tension and environmental nutrients. The most extensively studied of these parameters is the state of tumor oxygenation. Though the oxygen effect has been known since the early 1950's, its relevance to clinical radiocurability remains uncertain at this time. Newer diagnostic tools such as NMR and PET scanning may provide useful ways to monitor hypoxia and re-oxygenation in tumors undergoing radiation therapy. Other methods that may be useful in determining hypoxic cell fractions and their clinical implications include microprobes for intratumoral oxygen measurements and radioactively-labelled hypoxic cell sensitizers which have been shown to preferentially bind to hypoxic fractions of solid tumors in vitro.

This program is described in the Catalog of Federal Domestic Assistance No. 13-395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive order 12372 or Health Systems Agency review.

Studies of tumor cell characteristics are now possible through flow cytometry analysis. Such characteristics as cell ploidy, and identification of hetero-geneous subpopulations can now be investigated relatively reliably and rapidly. These techniques may be especially useful since additional techniques have been developed for "salvaging" paraffin-embedded biopsy specimens for use in flow cytometry analysis. This could allow large volumes of retrospective data to be analyzed in which the outcome of treatment is already known.

Some or all of the above-mentioned factors or other factors may be useful in predicting before, or shortly after, beginning radiation treatment whether or not the treatment will be successful in terms of cure or local control. This would allow a more rational selection process for both routine clinical applications and investigational treatment protocols.

The Radiation Research Program therefore invites grant applications to investigate the relationship of the previously-described factors, as well as other factors, to the curability of malignant tumors by radiation therapy in the clinical situation.

REVIEW PROCEDURES AND CRITERIA

Applications should be submitted on form PHS-398 (Rev 5/82) which is available in the institution's collaborative research or business office, otherwise an application kit may be obtained from the Office of Grants Inquiries, Division of Research Grants (DRG), NIH. The original and six copies of the application should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Upon receipt of the applications, the Referral Office, DRG will assign each application to a specific NIH institute, in this case NCI, for possible funding and to a Study Section composed mostly of non-Federal scientific consultants for scientific and technical merit review. Subsequently, the applications will be evaluated for program relevance by the NCI Advisory Board (NCAB). All applications recommended for approval will compete with other NCI regular (R01) approved grant applications for available funds.

The title of this announcement, "**Prediction of Tumor Response to Radiation Therapy**", should be typed under item 2 on page 1 of this application and the word "yes" should be checked to indicate a response to this announcement.

Application receipt dates are March 1, July 1, and November 1.

For further information contact:

Dr. Richard L. Cumberlin
Program Director
Radiotherapy Development Branch
Radiation Research Program
National Cancer Institute
National Institutes of Health
Landow Building - Room 8C08
Bethesda, Maryland 20205

Telephone: (301) 496-9360

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-HL-01-1-LSPECIALIZED CENTERS OF RESEARCH CONCERNED WITH RESPIRATORY DISORDERS OF NEONATES AND CHILDRENNATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR RESPIRATORY DISORDERS OF NEONATES AND CHILDREN

P.T. 34; K.W. 1201210, 1201020, 1200270, 1200180

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: September 2, 1985

The Division of Lung Diseases, National Heart, Lung, and Blood Institute, (NHLBI) supports a comprehensive research program dealing with respiratory disorders of neonates and children which includes both clinical and basic approaches directed at expediting the development and application of new knowledge essential for improved diagnosis, treatment, and prevention of these disease problems. As part of this comprehensive program, the NHLBI announces competition for Specialized Centers of Research (SCORs) and for National Research and Demonstration Centers (NRDCs) that focus on respiratory disorders of neonates and children. SCOR programs must contain both clinical and basic research activities, whereas a NRDC is envisioned as an enhancement of a SCOR through incorporation of demonstration and education research along with a coordination and integration component.

An applicant may submit a request for either a SCOR or a NRDC grant. An NRDC application may be awarded as a SCOR if, after peer review, the demonstration and education component and the integration component are judged to be weak while the clinical and basic research projects are favorably recommended. Applications received in response to this announcement will be part of a single competition.

Copies of the complete RFA may be obtained from:

Suzanne S. Hurd, Ph.D.
Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A16
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301)496-7208

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-02-L

SPECIALIZED CENTERS OF RESEARCH AND NATIONAL RESEARCH AND
DEMONSTRATION CENTERS

o CHRONIC DISEASES OF THE AIRWAYS

o OCCUPATIONAL AND IMMUNOLOGIC LUNG DISEASES

o PULMONARY VASCULAR DISEASES

P.T. 34; K.W. 1201210, 1002023, 0701034, 1200270, 1200180

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: December 2, 1985

The National Heart, Lung, and Blood Institute (NHLBI) Division of Lung Diseases, supports comprehensive research programs dealing with: (i) chronic diseases of the airways; (ii) occupational and immunologic lung diseases; and (iii) pulmonary vascular diseases. These comprehensive research programs are intended to include both clinical and basic approaches directed at expediting the development and application of new knowledge essential for improved diagnosis, treatment, and prevention.

The NHLBI announces competition for Specialized Centers of Research (SCORs) and National Research and Demonstration Centers (NRDCs) that focus on one of these disease categories or research areas. A SCOR program must contain both clinical and basic research activities, whereas a NRDC is envisioned as an enhancement of a SCOR through incorporation of demonstration and education research along with a coordination and integration component.

An applicant may submit a request for either a SCOR or a NRDC grant dealing with chronic diseases of the airways, or occupational and immunologic lung diseases, or pulmonary vascular diseases. A NRDC application may be awarded as a SCOR grant if, after peer review, the demonstration and education component and the integration component are judged to be weak while the clinical and basic research projects are favorably recommended. All applications resulting from this RFA will be part of a single competition.

Copies of the complete RFA may be obtained from:

Suzanne S. Hurd, Ph.D.
Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A16
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301)496-7208

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-03-B

INHIBITOR FORMATION IN HEMOPHILIA

P.T. 34; K.W. 1200680, 1200200, 1200560, 1002019, 1003002, 0201058

DIVISION OF BLOOD DISEASES AND RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Blood Diseases Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA, 85-HL-3-B, may be obtained from staff of the NHLBI.

The program will encourage research addressing fundamental questions concerning the development of inhibitors to factors VIII and IX in hemophilia and to determine what measures may prevent or modify the immunologic response. It is expected that the approach to these questions will be an immunological one but that collaborative research among disciplines such as hematology, immunohematology, genetics, biochemistry and veterinary medicine may be required.

Requests for copies of the RFA should be addressed to:

Carol H. Letendre, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5A12
Bethesda, Maryland 20205

Telephone: (301) 496-5911

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-04-L

ENDOTHELIAL AND SMOOTH MUSCLE CELL INTERACTIONS IN LUNG

P.T. 34; K.W. 1201210, 1003002, 1002023, 1002034, 0701038, 1201000, 1002004

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on pulmonary vascular endothelial and smooth muscle cell interactions in the normal and injured lung. The primary purpose of this program is to better define the role of the endothelium in modulating the response of vascular smooth muscle to endogenous and exogenous stimuli.

Specific objectives of this program include: 1) determine the role of endothelial cells in modulating vascular tone in response to endogenous and exogenous vasoactive agents; 2) determine the effects of endothelial injury on endothelial-smooth muscle cell interactions; 3) improve understanding of mechanisms leading to pulmonary hypertension; and 4) provide the basis for developing new approaches to vasodilator therapy. This announcement may be of particular interest to investigators with expertise in biochemistry, immunology, physiology, pharmacology, pathology, and cell biology.

A letter of intent is requested by January 15, 1985 and the deadline for receipt of applications is April 1, 1985. The earliest award date for successful applicants will be in September 1985. Requests for copies of this RFA should be addressed to:

Carol E. Vreim, Ph.D.
Chief, Interstitial Lung Diseases Branch
Division of Lung Diseases, NHLBI
National Institutes of Health
Westwood Building - Room 6A05
Bethesda, Maryland 20205

Telephone: (301) 496-7034

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-05-H

JUVENILE HYPERTENSION AND THE PREHYPERTENSIVE STATE

P.T. 34; K.W. 1200600, 1201020, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The Hypertension and Kidney Diseases Branch, Division of Heart and Vascular Diseases (DHVD), National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above program.

The proposed program, "Juvenile Hypertension and the Prehypertensive State", will provide support for approximately ten research projects for a period of five years, after which it is anticipated that the grantees will continue to compete through regular support mechanisms. Each application should focus on multidisciplinary investigations seeking to elucidate mechanisms of blood pressure regulation and hypertension in the young (children and/or animal models), to identify individuals who will develop systemic hypertension as adults, and to improve the medical management of juvenile hypertension. The staff for these undertakings will consist of investigators within the spectrum of laboratory and clinical skills related to hypertension research. Of the clinical research skills, those in pediatric hypertension are especially sought.

Requests for copies for the RFA should be addressed to:

Dr. John B. Dunbar
Hypertension & Kidney Diseases Branch
National Heart, Lung, & Blood Institute
National Institutes of Health
Federal Building - Room 4C08
Bethesda, Maryland 20205

Telephone: (301) 496-1857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-06-H

BLOOD VESSELS OF THE BRAIN AND NECK

P.T. 34; K.W. 1200220, 1200240, 1002034, 0701038, 1200270, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The Hypertension and Kidney Diseases Branch, Division of Heart and Vascular Diseases (DHVD), National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a request for applications (RFA) on the above program.

The proposed program, "Blood Vessels of the Brain and Neck", will provide support for approximately ten research projects for a period of five years, after which it is anticipated that the grantees will continue to compete through regular support mechanisms. Each application should focus on research involving one or more of the vascular aspects of cerebrovascular disease in human subjects or in animal models. Among the disciplines and expertise that may be appropriate for this research program are physiology, pharmacology, pathology, biochemistry, biophysics, neurology, endocrinology, and other clinical specialties related to hypertension and atherosclerosis, blood dyscrasias, and others.

Requests for copies for the RFA should be addressed to:

Dr. John B. Dunbar
Hypertension & Kidney Diseases Branch
National Heart, Lung, & Blood Institute
National Institutes of Health
Federal Building - Room 4C08
Bethesda, Maryland 20205

Telephone: (301) 496-1857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-07-H

CELL BIOLOGY OF THE VASCULATURE IN THE PATHOGENESIS OF HYPERTENSION

P.T. 34; K.W. 1200600, 1002004, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The Hypertension and Kidney Diseases Branch, Division of Heart and Vascular Diseases (DHVD), National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above program.

The proposed program, "Cell Biology of the Vasculature in the Pathogenesis of Hypertension" will provide support for five to ten grants for a period of five years, after which it is anticipated that the grantees will continue to compete through regular support mechanisms. Each application should focus on one or more interdisciplinary investigation(s) of the vasculature in hypertension utilizing a cell biology approach. The ideal staff of these grants will consist of experienced cell biologists and experienced hypertension investigators who are willing to interact in this research program.

Requests for copies for the RFA should be addressed to:

Mr. Armando Sandoval
Hypertension & Kidney Diseases Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C08
Bethesda, Maryland 20205

Telephone: (301) 496-1857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-08-H

MOLECULAR GENETICS AND HYPERTENSION

P.T. 34; K.W. 1200600, 1002019, 1002008, 1002004, 1002034, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The Hypertension and Kidney Diseases Branch, Division of Heart and Vascular Diseases (DHVD), National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above program.

The proposed program "Molecular Genetics and Hypertension" will provide support for five to ten grants for a period of five years, after which it is anticipated that the grantees will continue to compete through regular support mechanisms. Each application should focus on one or more interdisciplinary investigations dealing with molecular genetics in hypertension. Among the disciplines and expertise that may be appropriate for this research program are molecular biology, genetics, physiology, biochemistry, cell biology, and clinical specialities related to hypertension.

Requests for copies for the RFA should be addressed to:

Mr. Armando Sandoval
Hypertension and Kidney Diseases Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C08
Bethesda, Maryland 20205

Telephone: (301) 496-1857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-09-H

CELLULAR AND MOLECULAR BIOLOGY OF THE ATHEROSCLEROTIC LESION

P.T. 34; K.W. 1200235, 1002004, 1002008, 1002027, 1002023, 1003002, 1201000, 0201058

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date April 2, 1985

The Lipid Metabolism and Atherogenesis Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute announces the availability of a Request for Applications (RFA) on the above subject.

Applications are sought that will apply the methods of cellular and molecular biology to study the mechanisms that underlie the formation of atherosclerotic lesions.

A wide variety of disciplines may be appropriate including cellular, molecular and developmental biology, virology, microbiology, genetics, oncology, immunology, biochemistry, pathology and veterinary medicine. Expertise in atherogenesis will be required and interdisciplinary research associations among investigators in one or more of the above fields and atherosclerosis is encouraged.

The mechanism of support will be the traditional NIH research grant (R01). About eight to ten awards are anticipated to result from this request.

Copies of the RFA and further information may be obtained by contacting:

Dr. Edwin C. Gangloff
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 4C12
National Institutes of Health
Bethesda, Maryland 20205

Telephone (301) 496-1978

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-10-H

SPECIALIZED CENTERS OF RESEARCH IN ARTERIOSCLEROSIS (SCOR-A) AND
NATIONAL RESEARCH AND DEMONSTRATION CENTERS IN ARTERIOSCLEROSIS
(NRDC-A)

P.T. 04, 34; K.W. 1200235, 1200270, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application receipt date: September 16, 1985

The Lipid Metabolism Atherogenesis Branch of the Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subjects.

The Division invites applications for Specialized Centers of Research (SCOR) in Arteriosclerosis. At the same time, it invites with this request proposals from institutions with the capability for both SCOR and demonstration and education research to apply for National Research and Demonstration Centers in Arteriosclerosis.

The Centers are large, multidisciplinary research activities that have a thematic relationship among their various parts. The SCOR must contain both basic and clinical activities while the NRDC comprises the full research spectrum of basic, clinical, demonstration and educational research together with activities that provide integration of the component parts.

The application receipt date is September 16, 1985 and the award date is expected to be December 1, 1986. Subject to the availability of funds, it is presently anticipated that about eight to ten awards can be made of which two or three may be NRDC in Arteriosclerosis.

A detailed description of the nature of the Centers, their scope, administration and the method of application is contained in the RFA which is available from the address below. In addition, there is available a 12-page brochure on the Guidelines for Demonstration and Education Research Grants prepared by the Institute that can be helpful to prospective applicants.

Requests for copies of the RFA should be addressed to:

G. C. McMillan, M.D., Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 406
Bethesda, Maryland 20205

Telephone (301) 496-1613

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-11-H

STUDIES ON THE SEX DIFFERENCES IN CORONARY ARTERIOSCLEROSIS AND THE
POSSIBLE ROLES OF SEX STEROIDS

P.T. 34; K.W. 1200235, 1200440, 1003002, 1200180, 0411005, 1200563

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date January 15, 1985

The Lipid Metabolism-Atherogenesis Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are available from the address listed below.

The research objectives of this program are to elucidate reasons why the severity of coronary arteriosclerosis and the frequency of heart attacks differ in men and women and to study the possible role(s) of sex steroids, particularly estrogen in these differences. To these ends studies at the cellular, tissue, and animal levels and clinical investigation are appropriate. Many different kinds of disciplines and expertise are appropriate including, for example, cellular biology, steroid, protein and connective tissue biochemistry, blood coagulation and thrombotic processes, metabolism, and clinical investigation, knowledge of experimental atherosclerosis especially in nonhuman primates, and expertise in plaque pathology and pathogenesis.

The request excludes epidemiology and clinical trials. Studies on sex steroids without reasonable association with arteriosclerosis, heart attack, risk factors or pathogenetic mechanisms for cardiovascular disease will not be responsive to the request.

Request for copies of the RFA should be addressed to:

Ms. Irma Mebane
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 401
Bethesda, Maryland 20205

Telephone (301) 496-1681

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-12-L

AIRWAY SMOOTH MUSCLE: BIOLOGY AND PHARMACOLOGY

P.T. 34; K.W. 1201210, 1003002, 1002004, 0701038, 1201000, 1200890

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 15, 1985

The Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the biology and pharmacology of airway smooth muscle in health and disease. The main objective of this special grant program is to stimulate research on the morphological, physiological, pharmacological and other functional correlates of airway smooth muscle in normal conditions and various pulmonary diseases.

Some specific objectives of this program include the characterization of: the structural features, innervation, and spatial distribution of the surface macromolecules of airway smooth muscle, the morphological correlates of the neurogenic control, and the agents and the regulatory mechanisms leading to the reversible bronchoconstriction in humans and animals in health and pulmonary disease. This announcement may be of particular interest to investigators with expertise in cell biology, pharmacology, biochemistry, cell physiology, pathology and neurophysiology.

A letter of intent is requested by February 15, 1985 and the deadline for receipt of applications is April 15, 1985. The earliest award date for successful applicants will be in September 1985. Requests for copies of this RFA should be addressed to:

J. Sri Ram, Ph.D.
Chief, Airways Disease Branch

or

Dorothy Berlin Gail, Ph.D.
Chief, Structure & Function Branch

Telephone: (301) 496-7332

Telephone: (301) 496-7171

Division of Lung Diseases, NHLBI
National Institutes of Health
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-13-L

MINORITY SUMMER PROGRAM IN PULMONARY RESEARCH

P.T. 34; K.W. 1201210, 1200170, 1200180

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 1, 1985

The Prevention, Education, and Manpower Branch of the Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will encourage qualified minority school faculty members and graduate students to develop interests and skills in research in pulmonary diseases at established pulmonary training centers. It will also stimulate pulmonary research by offering minority school faculty members and students the opportunity to enhance their research capabilities at domestic institutions which offer superior opportunities in this area.

Requests for copies of the RFA should be addressed to:

Joan Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A12
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-14-H

MYOCARDIAL PROTEINS IN CARDIAC DISEASES

P. T. 34; K.W. 1200235, 1201150, 1201190, 1200180

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: January 15, 1985

The Cardiac Diseases Branch in the Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support basic research on the identification, isolation, characterization, and quantification of proteins from diseased human hearts. Specifically, the program is intended to encourage the rapid application of developing technologies to indepth studies of proteins from diseased hearts as a means of better understanding the pathogenesis of irreversible heart disease. Among the disciplines that may be appropriate for this research program are biochemistry, pathology, pharmacology, physiology, cell biology, molecular biology, genetics, cardiology, and surgery. Areas of expertise that may be relevant include biochemistry, cardiac pathology, muscle physiology, recombinant DNA technology, and cardiac performance.

Requests for copies of the RFA should be addressed to:

Dr. Michael C. Lowe
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 3C06
Bethesda, Maryland 20205

Telephone: (301) 496-1081

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****85-HL-15-B****MECHANISMS OF PLATELET REFRACTORINESS**

P.T. 34; K.W. 1200200, 1002023, 1002034

DIVISION OF BLOOD DISEASES AND RESOURCES**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: February 15, 1985

The Blood Resources Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) 85-HL-15-B on the above subject. Copies of the RFA may be obtained from staff of the NHLBI.

The program will encourage research to elucidate the immunologic and physiologic mechanisms of refractoriness of platelet transfusions. The effectiveness of platelet transfusion to control bleeding in thrombocytopenic patients has been well established. Due to progress in platelet therapy and in the preparation and preservation of platelets, the number of platelet concentrate transfusions has increased dramatically over the last ten years. However, in spite of HLA matching of donors and recipients, platelet refractoriness has become a major limitation to effective long-term platelet support in a significant number of patients. The mechanisms producing these refractory states are unknown but are presumed to be related to immunologic reactions as yet unidentified, to consumptive coagulopathies, or to other mechanisms.

This solicitation represents a major effort by the NHLBI to identify the indications, effectiveness and factors that may modify the response to transfused platelets. Other than the relevance of HLA antigens to platelet compatibility, little is known about specific platelet antigen systems. Likewise, information is incomplete on the extent to which consumptive coagulopathy may contribute to refractoriness and how it may be controlled. Such information should make possible the evaluation of various patient management regimens, resulting in a prolongation of effective platelet support.

Requests for copies of the RFA should be addressed to:

Luiz H. Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5C10
Bethesda, Maryland 20205

Telephone (301) 496-1537

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-17-H

MOLECULAR MECHANISMS CONTROLLING MYOCARDIAL GROWTH AND
HYPERTROPHY

P.T. 34; K.W. 1200240, 1002008, 1002006, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: March 15, 1985

The Cardiac Functions Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject.

This program will support research applying the recent advances in molecular and cellular biology to the study of the basic mechanisms underlying myocardial growth and the development of myocardial hypertrophy. This announcement may be of particular interest to investigators in disciplines which include biochemistry, cardiology, cellular biology, developmental biology, genetics, molecular biology, and physiology.

Requests for copies of the RFA should be addressed to:

Stephen C. Mockrin, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 304
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1627

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****85-HL-18-H****FUNDAMENTAL STUDIES OF NORMAL AND ABNORMAL CARDIAC RHYTHM**

P.T. 43; K.W. 1200240, 1002034, 1002001, 1200875, 1200180

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Cardiac Diseases Branch in the Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from NHLBI staff.

The major purpose of this special grant program is to stimulate comprehensive multidisciplinary investigations into the genesis of normal cardiac rhythm and the mechanisms underlying dysrhythmias, particularly those induced by myocardial ischemic injury. Members of departments of anatomy, physiology, cellular biology, molecular biology, pharmacology, cardiology, neurology, surgery, and behavioral medicine may be interested in responding individually or jointly to this RFA.

Requests for copies of the RFA should be addressed to:

Dr. Elliott C. Kulakowski
Cardiac Diseases Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 3C06
Bethesda, Maryland 20205

Telephone: (301) 496-1081

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-19-P

CHILDHOOD NUTRITION, PHYSICAL ACTIVITY, AND CV HEALTH

P.T. 34; K.W. 0202022, 1200240, 1200180, 0404000, 0414007, 0404004

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Prevention and Demonstration Research Branch of the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support prospective research studies that will identify and track the acquisition of food intake and physical activity patterns related to cardiovascular health in children three or four years of age at entry into a study. Children from families with a high risk for coronary heart disease or stroke would be compared with children from families with a low risk for these diseases. It is expected that the research projects will require expertise from the biomedical, social, and behavioral disciplines including cardiology, pediatrics, nutrition, physiology, epidemiology, experimental psychology, social psychology, education psychology, and medical anthropology.

Request for copies of the RFA should be addressed to:

Elaine J. Stone, Ph.D.
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building - Room 6A-12
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-2465

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-20-P

EXERCISE, STRESS AND ATHEROSCLEROSIS

P.T. 34; K.W. 0701046, 1200235, 1200440

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1984

The Behavioral Medicine Branch of the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

The special grant program will support research investigating the role of physical exercise as a potential mediator of the effects of stress on the development and progression of atherosclerosis. Preliminary evidence on the moderating effects of exercise on cardiovascular and neuroendocrine responsivity to environmental demand has suggested potential common pathways for mechanism of action. Elucidation of this relationship will require the development of appropriate animal models to adequately control for genetic, dietary, developmental and environmental variables. Multidisciplinary approaches involving the above fields are strongly encouraged.

Requests for copies of the RFA should be addressed to:

Stephen M. Weiss, Ph.D.
Behavioral Medicine Branch
National Heart, Lung, and Blood Institute
Federal Building - Room 604
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9380

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-21-P

SMOKING CESSATION IN PATIENTS WITH CARDIOVASCULAR DISEASE

P.T. 34; K.W. 1200235, 0404019, 0414000, 041700, 1200230, 0701032

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Behavioral Medicine Branch of the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This special grant program will support biobehavioral research on smoking cessation and maintenance of cessation within the specialized population of patients with diagnosed cardiovascular disease. Studies seeking to develop and evaluate interventions tailored to the needs of this specific population in attaining long-term smoking abstinence are encouraged, and may encompass approaches from the fields of psychology, sociology, physiology, nursing, and cardiology.

Requests for copies of the RFA should be addressed to:

Peter G. Kaufmann, Ph.D.
Behavioral Medicine Branch
National Heart, Lung, and Blood Institute
Federal Building - Room 604
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9380

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-22-P

BEHAVIORAL STRESS, NEUROACTIVE PEPTIDES, AND CARDIOVASCULAR DISEASE

P.T. 34; K.W. 0701046, 1200235, 1201020, 1200440, 1200180

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Behavioral Medicine Branch of the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This special grant program will support research explicating the relationship of behavioral stress to cardiovascular function in health and disease, specifically as mediated by the new family of neuroactive peptides. Clinical studies, as well as laboratory investigations utilizing either human subjects or animal models are encouraged, and may encompass approaches from the fields of anatomy, behavior, physiology, pharmacology, physiology, endocrinology, neuroscience and pathology.

Requests for copies of the RFA should be addressed to:

Peter G. Kaufmann, Ph.D.
Division Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building - Room 604
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9380

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-23-P

WORKPLACE DEMONSTRATION AND EDUCATION RESEARCH IN CARDIO-
VASCULAR DISEASES

P.T. 34; K.W. 1200235, 0502017, 0701042, 0411005, 1010013, 0701013

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Prevention and Demonstration Research Branch, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of this RFA are currently available from staff of the NHLBI.

This program will support demonstration and education research projects on risk factor reduction for cardiovascular diseases (CVD) in the workplace. Each intervention project should include studies of intervention on two or more major risk factors for these diseases. Each applicant must agree, if successful, to work along with other successful applicants on the primary purpose to test whether successful major risk factor interventions for CVD can be adapted to the workplace and shown to be clinically and behaviorally effective. In addition, each applicant may choose one or more of the following research areas to pursue in the workplace:

To compare strategies for implementing single risk factor modification approaches to intervention with strategies to modify two or more major CVD risk factors. The effect on variables, such as participation rates and logistic risk scores for individuals and for all employees in the study site, as well as the effects on specific risk factors, could be assessed. A third control group without intervention could also be part of the design.

To test selected health education approaches to enhance compliance to interventions on one or more CVD risk factors.

Staffing and consultation for the research should include health care professionals experienced in working with industries, and in the CVD field, trained technicians, health educators and counsellors, a biostatistician, an epidemiologist, and data processing and support staff.

The populations in which the research would be conducted would be employees of intermediate size companies that include a large proportion of blue collar and hourly paid workers.

Research designs should be experimental or quasi-experimental. The plans for analysis to be done appropriate to the research design, must be included in the application. Budgets should include four trips to Bethesda and eight days per diem the first year for investigators to develop together standardized screening approaches where appropriate. Budgets for subsequent years should allow two trips to Bethesda and four days per diem each year for sharing experiences and results and refining methods. Applicants must indicate their willingness to attend and participate in these meetings and to show plans and proposed methods and to agree to carry out standardized assessments agreed upon by the successful applicants (where feasible and appropriate).

Request for copies of the RFA should be addressed to:

Gerald H. Payne, M.D., M.P.H.
Federal Building - Room 6A14
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-2465

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-24-H

MINIMALLY INVASIVE TECHNIQUES FOR CHARACTERIZATION OF

ATHEROSCLEROTIC PLAQUE

P.T. 34; K.W. 1200235, 1200370, 0603000, 1004019, 0607024, 1200180

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: January 15, 1985

This grant program will support basic research and development of new and improved techniques to identify and quantify components of atherosclerotic plaque in arteries. It is expected that research projects will encompass a variety of approaches such as ultrasound, nuclear medicine, x-ray, and nuclear magnetic resonance. Disciplines that may be appropriate for this research program are atherogenesis, biochemistry, bioengineering, blood coagulation, cardiology, cellular biology, chemistry, nuclear medicine, pathology, physics, radiology, surgery, or others. Of particular value may be expertise in nuclear magnetic resonance, ultrasound, and x-ray methodologies, tracer techniques applicable to the plaque, and biology of the plaque.

The Devices and Technology Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

Request for copies of the RFA should be addressed to:

Alan S. Berson, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 312
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1586

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-25-P

RESEARCH IN NUTRITION AND CARDIOVASCULAR DISEASES

P.T. 34; K.W. 0202022, 1200235, 1200600, 1200930, 1200180

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 15, 1985

The Prevention and Demonstration Research Branch of the DECA, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support research in nutrition and CVD, including basic, clinical, behavioral, and demonstration and education research. There shall be a central theme for proposed investigations and component scientific projects which relate to it, and which also complement or contribute to one another. Since many approaches are possible, this research may be of interest to investigators in a variety of disciplines such as cardiology, physiology, biochemistry, epidemiology, pediatrics, nutrition, behavioral sciences, and public health, with particular expertise in hyperlipidemia, hypertension and obesity.

Request for copies of the RFA should be addressed to:

Marilyn Farrand, R.D.
Division of Epidemiology and Clinical Applications
Federal Building - Room 6A08
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-3503

ANNOUNCEMENT

PREVENTIVE CARDIOLOGY ACADEMIC AWARD

P.T. 34; K.W. 1200230, 0701042, 1200235, 0502024

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The Division of Epidemiology and Clinical Applications (DECA) of the National Heart, Lung, and Blood Institute (NHLBI) has initiated the Preventive Cardiology Academic Award (PCAA) to provide a stimulus for the development of a preventive cardiology curriculum in those schools of medicine and osteopathy that do not have one and to strengthen and improve the preventive cardiology curriculum in those schools that do. Each school of medicine or osteopathy in the United States and its possessions or territories is eligible to compete for one award for a project period that does not exceed five years. The number of awards made each year will depend upon the merit of the applications received and availability of funds.

For the purposes of the PCAA, the term preventive cardiology is used to define the area of cardiovascular medicine having a special concern with the development of knowledge and the application of knowledge directed at the prevention of heart and vascular diseases. This includes the area of primary prevention of cardiovascular diseases in infants, children, and adults who are at risk of developing such diseases and the reduction of preventable complications or disability in persons who have already developed cardiovascular disease.

This award is intended to:

Encourage the development of a high quality preventive cardiology curriculum in schools of medicine and osteopathy that will significantly increase the opportunities for students and house staff to learn both the principles and practice of preventive cardiology; develop promising faculty whose interest and training are in preventive cardiology teaching, research, and practice; develop established faculty who have a major commitment to and possess educational skills for teaching preventive cardiology;

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

Facilitate interchange of educational ideas and methods applicable to teaching preventive cardiology among awardees and institutions;

Develop at the grantee institution the ability to strengthen continuously the improved preventive cardiology curriculum, with local funds, subsequent to the award.

Requests for copies of the PCAA Program Guidelines should be directed to:

Curt Furberg, M.D.
Acting Associate Director
Clinical Applications and Prevention Program
Division of Epidemiology and Clinical
Applications
National Heart, Lung, and Blood Institute
Federal Building - Room 216
Bethesda, Maryland 20205

Telephone: (301) 496-3107

ANNOUNCEMENT

RESEARCH CAREER DEVELOPMENT AWARD IN BASIC SCIENCE RELATED TO THE
RESPIRATORY SYSTEM

P.T. 34; K.W. 1201210, 1003002, 1002023, 1002019, 1002008, 1200180

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: February 1, June 1, October 1

The Division of Lung Diseases of the National Heart, Lung, and Blood Institute (NHLBI) supports the career development of research investigators through the Research Career Development (RCDA) program, an NIH-wide mechanism. The career development of investigators interested in basic research is an important part of the program of the Division of Lung Diseases, and this program announcement is intended to focus attention on this important area.

In the past ten years, major advances in genetics, immunology, biochemistry, and molecular biology have taken place and have contributed to the understanding of a number of disease processes. Although pulmonary research has benefited from these advances to some extent, the potential still exists for basic science contributions to pulmonary research. For example, the influence of genetics and inherited factors in respiratory disease is not well understood. The biochemical properties of mediators involved in the regulation of airway smooth muscle function in health and disease also need to be investigated further. Similarly, more work is needed to elucidate the metabolism of peptides, amines, lipids, and other substances by the lung and the role of the prostaglandins and other mediators in injury and repair processes of the normal and diseased lung. To further develop and stimulate research in these important areas, approaches involving geneticists, biochemists, and other basic scientists should be encouraged.

The objective of this announcement is to encourage basic scientists to gain experience in the basic science aspects of pulmonary research. The awards are available for persons whose research potential is apparent, but who need additional experience in a productive scientific environment conducive to the development of a career in independent research. The initiative will encourage scientists in disciplines including, but not limited to, biochemistry, molecular biology, genetics, and immunology to interact with pulmonary researchers in the conduct of pulmonary research. The award will provide five years of research experience to an individual who has a doctoral degree, at least 3 years of subsequent relevant research or professional experience, and who meets the other eligibility criteria for an RCDA from NIH.

This program is described in the Catalog of Federal Domestic Assistance No. 13.838, Lung Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

APPLICATION SUBMISSION AND REVIEW

Application receipt dates for new applications are the regular application receipt dates for NIH Research Career Development Award (RCDA) applications of February 1, June 1, and October 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS 398 and consult the "Policy Brochure and Additional Instructions for Preparing an Application for a National Institute of Health Research Career Development Award" in developing an application. Both of these are available at most institutional business offices or from the Division of Research Grants (DRG) NIH.

To identify responses to this announcement, check "yes" and write "**Research Career Development Award in Basic Science Related to the Respiratory System**" under item 2 of page 1 of those grant applications relating to this topic.

The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Joan Wolle, Ph.D.
Prevention, Education, and Manpower Branch
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 6A12
Bethesda, Maryland 20205

Telephone: (301) 496-7668

ANNOUNCEMENT

MINIATURIZED TRANSDUCERS FOR IMAGING AND MEASURING CARDIOVASCULAR
STRUCTURE AND FUNCTION IN INFANTS AND IN THE YOUNG

P.T. 34; K.W. 1200380, 1004019, 1201020, 0603000

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: March 1, July 1, November 1

Pediatric cardiology is an important sector of several programs in the Division of Heart and Vascular Diseases(DHVD) of the National Heart, Lung, and Blood Institute (NHLBI). Diagnostic instrumentation for detection and evaluation of heart and vascular diseases is supported in the Division.

Research and development has traditionally been conducted for application to the adult population. As a result, physical features and performance of existing instruments often inhibit or prevent their application to infants or young children. As an example, a typically well designed, externally applied transducer to detect blood flow may be perfectly acceptable for use in an adult, but cannot be applied properly at a rib interspace in a small child. For an ultrasonic device, bone interference could prevent transmission and receiving of acoustic signals. As another example, if one were interested in imaging certain arterial structures, resolution of 1-2 mm may be adequate for an adult but, because this structure is 1/2 to 1/3 the size in an infant, such resolution may be entirely unacceptable for use with an infant.

The intent of this announcement is to encourage research involving externally applied transducers for imaging and measuring cardiovascular structure and function in infants and in the young. Indwelling transducers for use in the young are also of interest.

Applications should ideally propose to address a physiological or medical research problem to test and validate the instrumentation. Applications may include human and/or animal studies involving infants, young children, or early developmental stages.

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 73-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

APPLICATION SUBMISSION AND REVIEW

Application receipt dates for new regular research applications (ROIs) are the regular application receipt dates of March 1, July 1, and November 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS 398, which is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and put **"Miniaturized Transducers for Imaging and Measuring Cardiovascular Structure and Function in Infants and in the Young"** under item 2 of page 1 of those grant applications relating to the topics identified herein. The completed application (original plus five copies) should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for review according to the NIH process for regular research grant applications.

Additional information may be obtained by contacting:

Alan S. Berson, Ph. D.
Devices & Technology Branch
Division of Heart and Vascular Diseases
National Institutes of Health
Federal Building - Room 312
Bethesda, Maryland 20205

Telephone: (301) 496-1586

One additional copy of the application should be sent to Dr. Berson.

SMALL BUSINESS INNOVATIVE RESEARCH (SBIR) PROGRAM

Anyone interested in responding to this announcement through the SBIR program should request the Omnibus Solicitation for SBIR from:

Office of Grants Inquiries
Division of Research Grants
Westwood Building - Room 449
Bethesda, Maryland 20205

The Omnibus Solicitation contains information about the SBIR program, an application form and instructions how to apply. Questions regarding the Miniaturized Transducers Program should be addressed to Dr. Alan S. Berson whose address and phone number appear above.

ANNOUNCEMENT

ARRHYTHMIA DETECTION AND DISCRIMINATION FROM ELECTROGRAMS

T. 34; K.W. 1200370, 1004019, 0603006

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: March 1, July 1 and November 1

The objective of this announcement is to encourage research in the detection of arrhythmias from electrograms and in the development of algorithms for differential diagnosis among both atrial and ventricular rhythm abnormalities.

Detection and diagnosis of cardiac rhythm abnormalities based upon electrocardiographic signals have been a developing area since the early days of electrocardiography. Although most of the frequently observed arrhythmias are distinguishable from one or more ECG leads, differential diagnosis remains a problem for several of the less common arrhythmias. Basic physiologic mechanisms responsible for many of these arrhythmias are much less understood. In recent years, investigators have been directing efforts at arrhythmia detection from electrograms. A principal aim of these efforts has been to develop means for automatically detecting ventricular fibrillation so as to defibrillate an animal or human patient (some times without manual intervention) using totally implanted electronic circuitry. Other investigators have been interested in detecting rhythm abnormalities other than ventricular fibrillation using implanted circuitry for automatic cardioversion or defibrillation.

In September, 1983, a Workshop on this subject was held at the National Institutes of Health (NIH) supported by the National Heart, Lung, and Blood Institute (NHLBI) entitled Electrical Control of Tachyarrhythmias by Implantable Devices. Among the gap areas identified by the Workshop participants was the recognition that detection of arrhythmias by electrograms is in need of much additional research. Typical examples of unknowns are: Is it possible using suitable electrogram leads to allow differential diagnosis among various arrhythmias which cannot be well distinguished with surface ECG leads? How well can algorithms developed on the basis of surface ECG leads be adapted to electrograms? What type of electrodes should be used and how many leads and locations are optimum? Applicants are encouraged to consider these and other research questions related to this topic.

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 73-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The ability to successfully diagnose specific rhythm abnormalities from electrograms is likely to have a considerable impact on health care. Technologic advancements have made it possible to design sophisticated electronic circuitry compact enough to totally implant a system which can both detect rhythm abnormalities and apply electrical stimuli to interrupt an arrhythmia and convert cardiac activity back to normal rhythm. Such electrical conversion has the potential for being specific and for permitting continuous monitoring and application of properly timed and shaped electrical stimuli. Thus, rather than wait until the onset of a life-threatening ventricular arrhythmia, corrective action can be taken much earlier.

Research applications should ideally propose a hypothesis related to this topic and an experimental plan to test and validate the hypothesis. Theoretical, animal, and human studies may be appropriately included.

Application Submission and Review

Application receipt dates for new regular research applications (ROIs) are the regular application receipt dates of March 1, July 1, and November 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS 398, which is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and put **"Arrhythmia Detection and Discrimination from Electrograms"** under item 2 of page 1 of those grant applications relating to the topics identified herein.

The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Alan S. Berson, Ph. D.
Devices & Technology Branch
Division of Heart and Vascular Diseases
National Institutes of Health
Federal Building - Room 312
Bethesda, Maryland 20205

Telephone: (301) 496-1586

ANNOUNCEMENT

DEMONSTRATION AND EDUCATION RESEARCH RELATED TO PULMONARY DISEASE

P.T. 04; K.W. 1201210, 0502017, 0701042, 1200540, 0404000

NATIONAL, HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: March 1, July 1, November 1

Demonstration and education research is an integral part of the National Heart, Lung, and Blood Institute's (NHLBI) systematic approach to supporting research at the most basic level and then advancing these developments to the ultimate goal of improved health and health care for the nation. The NHLBI seeks to maintain an optimal balance in its support of various types of research. The Division of Lung Diseases of the NHLBI is particularly interested in stimulating more quality applications in the area of demonstration and education research related to pulmonary disease.

Demonstration and education research is the testing of the effectiveness of interventions to promote health or prevent disease in defined populations. The interventions selected for such testing should be those that have already been found to be efficacious in other studies and include, but are not limited to, education strategies and modifications in health care and health related practices. The studies should be based on the fields of biomedical, behavioral, and social sciences.

Demonstration and education research is the last phase of the five phases of the NHLBI biomedical research spectrum composed of: (1) basic research, which seeks new knowledge about normal and abnormal functions of the heart, lungs, and blood and the etiology and pathogenesis of their diseases; (2) applied research and development, which seeks to develop new ways of using basic research results to achieve specific practical goals, (3) clinical investigations, which evaluate the application of fundamental research results in the clinical setting, usually in a relatively small number of patients, (4) clinical trials, which determine the efficacy and safety of clinical interventions in samples of patients drawn from larger population groups, and (5) demonstration and education research, which determines the effectiveness of interventions designed to promote health or prevent disease in defined populations. The interventions selected for such testing should be those that have already been found to be efficacious in other studies and include, but are not limited to, education strategies and modifications in health care and health related practices.

The demonstration and education programs that the NHLBI intends to support are related to the provisions of the National Heart, Blood Vessel, Lung, and Blood Act of 1972 (Public Law 92-423, as extended by the Health Research and Health Service Amendments of 1976 (Public Law 94-278), the Biomedical Research Extension Act of 1977 (Public Law 95-83), and subsequent reauthorizations through 1980. These programs are described in the Catalog of Federal Domestic Assistance No. 13.838, Lung Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Topics which might be investigated in this program include, but are not limited to:

- o Education for cystic fibrosis patients and their parents to enhance their self-management of the disease.
- o Examination of the usefulness of peak-flow meters as an adjunct to health education for adult and pediatric asthmatics.
- o Development and evaluation of methods to encourage smoking cessation in those individuals diagnosed as having mild airflow obstruction or with chronic obstructive pulmonary disease.

The objective of this program announcement is to encourage grant applications for demonstration and education research into significant aspects of lung diseases. The population in which the research would be conducted should be well defined and may include health-care professionals, defined groups within a community, or the general population. Staffing for the research should include relevant professional expertise in disciplines as needed, including medical disciplines, health education, epidemiology, biostatistics, and behavioral and social sciences.

APPLICATION SUBMISSION AND REVIEW

Application receipt dates for new applications are the regular receipt dates of March 1, July 1, and November 1.

In preparing an application, potential applicants should consult the "Guidelines for Demonstration and Education Research Grants" (June 15, 1983) available from the National Heart, Lung, and Blood Institute Program Office listed below. Applicants should use the regular research grant application form PHS 398, which is available at most institutional business offices or from the Division of Research Grants (DRG) NIH.

To identify responses to this announcement, check "yes" and put **"NHLBI Demonstration and Education Research"** under item 2 of page 1 of those grant applications relating to the topics identified herein. The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications from the review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Sydney Parker, Ph.D., Chief
Prevention, Education, and Manpower Branch
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 6A12
Bethesda, Maryland 20205

Telephone: (301) 496-7668

ANNOUNCEMENT

CAREER DEVELOPMENT PROGRAMS FOR PHYSICIANS IN CARDIAC AND VASCULAR RESEARCH IN CEREBROVASCULAR DISEASE

P.T. 34; K.W. 1200235, 1200220, 1200180

NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Application Receipt Dates: February 1, June 1, October 1

The Division of Heart and Vascular Diseases, National Heart, Lung and Blood Institute, (NHLBI) supports research on the cardiac and vascular aspects of cerebrovascular disease. There is a need to increase the pool of basic and clinical investigators whose competence and interests embrace this important field of research. For example, there is need to investigate the regional differences in atherogenesis between the cerebral and coronary or iliaco-femoral arteries; the effects of hypertension on these vessels; thrombotic and embolic disorders; the effects of cardiac arrhythmias and chronic heart failure; the pathogenesis of aneurysms; and others.

The Institute announces its interest in receiving applications from physicians in this area. Application should be made to either of two existing programs designed to foster research training and experience for those with degrees in medicine.

The two programs are the Clinical Investigator Award and the Physician Scientist Award. The Clinical Investigator Award is designed to provide the opportunity for promising clinically-trained individuals to develop into independent biomedical investigators by investigating a well-defined problem under the guidance of a sponsor who is competent in the chosen area of research. The Physician Scientist Award is intended to encourage newly trained clinicians to develop independent research skills and experience in a fundamental science under the guidance of a sponsor who will provide the training in a basic scientific discipline for application to a research problem that may not yet be well defined. Annual receipt dates of February 1, June 1, and October 1 have been established with the earliest beginning dates of December 1, April 1 and July 1 respectively. Descriptions of these awards may be found in the NH Guide for Grants and Contracts, Volume 13, Number 8, June 29, 1984. Specific information concerning guidelines, eligibility, duration, stipends of the two programs can be obtained from:

Max A. Heinrich, Jr., Ph.D.
Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A12
Bethesda, Maryland 20205

Telephone: (301) 496-1724

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) has a Clinical Investigator Development Award (CIDA) for training in clinical research, including cerebrovascular disease. The availability of this award was announced in the NIH Guide for Grants and Contracts, Volume 13, Number 9, August 3, 1984.

ANNOUNCEMENT

MINIMALLY INVASIVE MEASUREMENT OF BLOOD PRESSURE IN THE HEART AND CENTRAL ARTERIES

P.T. 34; K.W. 1200370, 1004019, 0603000

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: March 1, July 1, and November 1

Diagnostic instrumentation for detection and evaluation of heart and vascular diseases is supported in the Division of Heart and Vascular Diseases (DHVD) of the National Heart, Lung, and Blood Institute (NHLBI). The intent of this announcement is to encourage research aimed at minimally invasive techniques to measure pressure in the chambers of the heart and in central arteries.

In many patients with cardiac disease, it is clinically important to know what pressures exist in right atrium, right ventricle, pulmonary artery, left atrium, left ventricle or aorta. Currently, pressures can be estimated with minimally invasive means in right atrium (jugular venous pressure) and aorta (sphygmomanometer). Right atrial pressure will be the same as right ventricular diastolic pressure except for the rare occurrence of tricuspid stenosis. None of the other pressures can be directly measured unless more invasive techniques are used.

Attempts to measure pressures with minimally invasive techniques have included measurements of time intervals, blood velocity, and ventricular wall thickness and diameter.

Apart from Doppler velocity measurements (which themselves are indirect measurements of pressures) on stenotic lesions, measurements are not of pressures but of ventricular responses to pressures. Because there is a great deal of variability of response, confidence intervals are very large. Furthermore, because inverse prediction is involved, the ability to predict pressure in a single individual has limits that are too wide to be useful. Doppler studies are based on physical principles directly related to valve orifice area and at present have to assume normal outputs; this assumption will lead to some variability.

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 73-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Research applications should ideally include a sound theoretical basis for the proposed minimally invasive pressure measurement method and an experimental plan to test and validate the system in models, animals and/or humans.

Application Submission and Review

Application receipt dates for new regular research applications (R01s) are the regular application receipt dates of March 1, July 1, and November 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS 398, which is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and put "**Minimally Invasive Measurement of Blood Pressure in the Heart and Central Arteries**" under item 2 of page 1 of those grant applications relating to the topic identified herein. The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Alan S. Berson, Ph. D.
Devices & Technology Branch
Division of Heart and Vascular Diseases
National Institutes of Health
Federal Building - Room 312
Bethesda, Maryland 20205

Telephone: (301) 496-1586

Small Business Innovative Research (SBIR) Program

Anyone interested in responding to this announcement through the SBIR program should request the Omnibus Solicitation for SBIR from:

Office of Grants Inquiries
Division of Research Grants
Westwood Building - Room 449
Bethesda, Maryland 20205

The Omnibus Solicitation contains information about the SBIR program, an application form and instructions how to apply. Questions regarding the minimally invasive blood pressure measurement program should be addressed to Dr. Alan S. Berson whose address and phone number appear above.

To identify responses to this announcement, check "yes" and put "**Development of Genetic Hypertensive Animal Models**" under item 2 of page 1 of the grant application. The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Armando Sandoval
Hypertension and Kidney Diseases Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C08
Bethesda, Maryland 20205

Telephone: (301) 496-1857

Small Business Innovative Research (SBIR) Program

Anyone interested in responding to this announcement through the SBIR program should request the Omnibus Solicitation for SBIR from:

Office of Grants Inquiries
Division of Research Grants
Westwood Building - Room 449
Bethesda, Maryland 20205

The Omnibus Solicitation contains information about the SBIR program, an application form and instructions how to apply. Questions regarding the genetic hypertensive model program should be addressed to Mr. Sandoval whose address and phone number appear above.

ANNOUNCEMENT

DEVELOPMENT OF GENETIC HYPERTENSIVE ANIMAL MODELS

P.T. 34; K.W. 1200600, 1200410, 1002019, 1002002

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: March 1, July 1 and November 1

The National Heart, Lung, and Blood Institute (NHLBI) supports numerous basic research projects dealing with many of the multiple facets of essential hypertension. Essential hypertension is believed to have a genetic component, which is polygenic in nature. Therefore, the phenotypic expressions (genetic traits) are many and varied. However, despite this genetic multiplicity most of the basic research has been done with one genetic hypertensive model, the Okamoto spontaneously hypertensive rat (SHR). This model appears relevant to human essential hypertension and it is readily available. Other genetic hypertensive models do exist (e.g. the New Zealand Rat), but they are far less accessible than the SHR. Because of these circumstances, virtually all scientific advisory groups that have assessed the research needs of the hypertension field have at one time or another recommended the development of new hypertensive models including genetic models.

This program announcement is to encourage the development of new genetic animal models of hypertension. To develop a model it is imperative that a breeder work with an investigator so that the finished product reflects the research need and is marketable. This announcement offers support for the development phase in the hope that once a genetic hypertensive model is established, private enterprise will take over and make it accessible to all investigators. With appropriate attention to detail, both the research value of the model and its marketability can be enhanced. The model should (1) facilitate research; (2) be healthy; and (3) be cost-effective. All animal species will be considered. This announcement pertains to the de novo development of animal models, as well as to refinement of animal models whose development is already underway but not yet completed. The input of a geneticist is desirable.

This announcement is addressed to animal breeders and hypertension investigators through the regular research grant program and also through the Small Business Innovative Research (SBIR) program.

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.



REGISTRATION FORM

8th Annual NIH Research Safety Symposium

Creating a Safe Environment for Biomedical
Support Services Personnel

January 10-11, 1985
Washington, D.C.

I will attend the symposium I will not attend the symposium

NAME: _____ TITLE: _____

AFFILIATION: _____

ADDRESS: _____

I will attend the luncheon

I will not attend the luncheon

Please forward hotel reservation card

PLEASE RETURN BY DECEMBER 10, 1984 TO:

Ms. Attrices D. Griffin
EXPAND ASSOCIATES, INC.
7923 Eastern Avenue - Suite 400
Silver Spring, Maryland 20910

Telephone: (301) 585-7400

NIH Guide for Grants and Contracts

Vol. 13, No. 12, November 9, 1984

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

CORRECTION

REVIEW PROCEDURES - REMINDER TO APPLICANTS

P.T. 34; K.W. 1014012

In the NIH Guide for Grants and Contracts, Vol. 13, No. 10, page 2, September 7, 1984, it was indicated that if principal investigators need to submit additional application materials to initial review groups prior to review and do not know the identity of the Executive Secretary or the Study Section, the materials should be sent to the Referral Section of the Referral and Review Branch of the Division of Research Grants. This should be corrected to state that applicants who have not received notification of Study Section assignment within six weeks following the receipt date and who need to communicate with NIH staff or submit additional materials should call the Referral Section for information before mailing anything. The number to call is (301) 496-7324.

NOTICENIH/FDA REGIONAL WORKSHOPS-PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0701028, 1014002

NATIONAL INSTITUTES OF HEALTH

FOOD AND DRUG ADMINISTRATION

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institution officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. The current schedule includes:

<u>DATE</u>	<u>LOCATION</u>	<u>CONTACT</u>
January 17, 1985	Los Angeles, CA	Dr. Harry Neustein Professor of Pathology Chairman of Institutional Review Board Children's Hospital of Los Angeles 4650 Sunset Boulevard Los Angeles, CA 90054 Telephone: (213) 669-2426
April 16-17, 1985	Kansas City, MO	Dr. Patricia Solbach Menninger Foundation Box 829 Topeka, KS 66601 Telephone: (913) 273-7500 Ext 5451

A final list of dates and locations will be published at a later date. For further information regarding education programs contact:

Roberta H. Garfinkle
Office for Protection from
Research Risks
National Institutes of Health
Building 31 - Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20205

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-NS-02BRAIN-IMAGING RESEARCH CENTERS

P.T. 04, 34; K.W. 0603000, 1200380, 1200220, 0701007, 1201260, 1200990, 1200180, 1200270

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application receipt date: February 15, 1985
Letter of intent receipt date: December 15, 1984

The Stroke and Trauma Program of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) announce the availability of a Request for Applications (RFA) for research center grant applications for support of Brain-Imaging Research Centers. The principal objective is to improve the understanding of central nervous system function and dysfunction utilizing brain imaging methodologies; it is not primarily oriented to the development of improved instrumentation. The NINCDS wishes to encourage investigators to utilize combinations of imaging capabilities to develop and refine scientific information concerning the living brain under dynamic conditions by using imaging modalities. Particularly encouraged is a special emphasis on magnetic resonance imaging (MRI) and its interrelationship with other methods for measuring biochemical events and anatomical changes within the brain.

I. ELIGIBILITY

The principal investigator must be an established leader in one of the areas related to neurological or communicative disorders research, such as neurology, neuroradiology, neurosurgery, otolaryngology, or nuclear medicine, with demonstrated capabilities in research program development and direction. The expected interrelated biomedical research projects included in an interdisciplinary center should be conducted by experienced scientists representing a variety of basic and clinical science disciplinary backgrounds. The content of individual components of a research center is critical; the research center program must be organized around a central research theme and be composed of a sufficient number of scientifically meritorious research activities to permit an effective collaborative effort among the participating investigators.

To be eligible for competition under the RFA, applicants must be able to document the existence of or potential for ongoing basic and clinical research related to central nervous system structure, function, and pathology; core research resources in such areas as basic neurosciences, neurology, communicative sciences, neurosurgery, nuclear medicine, neuroradiology, and radiopharmaceuticals; leadership by a principal investigator who is established and recognized in the utilization of imaging methodologies for research related to neurological and (or) communicative disease; and cooperation among investigators who have a variety of backgrounds and experience in imaging and in nervous system research. In addition,

core facilities for central nervous system investigation must be available to the team and might include capabilities such as EEG, CT, MRI, PET, SPI, evoked potential, and ultrasound equipment.

Applicants for research centers for central nervous system imaging must demonstrate not only the capabilities for generating and addressing important imaging-research questions but also a highly integrated cooperation. Although leads developed through CT or PET scanning are appropriate for further investigation, emphasis should be on the use of MRI or SPI as investigative modalities with the potential for demonstrating interactions and intercomparisons with other imaging modalities. An institution need not have a PET scanner as a prerequisite for application, but the investigators must clearly be aware of quantitative autoradiographic and PET research and must develop projects such that information derived can be compared and contrasted with information that PET might provide. Alternatively, collaborative arrangements with institutions having PET facilities might enhance the overall effort. In a research center, it is usual for the component projects to encompass basic research, such as the development of chemicals for localization of function; applied research, such as animal studies that can indicate feasibility; and clinical research, including appropriate patient material with and without disease processes.

II. MECHANISM OF SUPPORT

The support mechanism for this program will be the investigator-initiated center grant. The NINCDS will not provide funds for the purchase and installation of major pieces of equipment, such as cyclotrons or MRI equipment.

III. INQUIRIES

Requests for copies of the RFA and inquiries regarding this announcement may be directed to:

Dr. George N. Eaves
Federal Building - Room 8A13
National Institutes of Health
Bethesda, Maryland 20205

Telephone: 301-496-4226

NOTICE

TISSUE BANKING AND DISTRIBUTION PROGRAM

UNIVERSITY OF WASHINGTON REGIONAL PRIMATE RESEARCH CENTER

P.T. 36; K.W. 1200140, 1201280

DIVISION OF RESEARCH RESOURCES

The Tissue Banking and Distribution Program at the University of Washington Regional Primate Research Center provides tissue and fluid specimens from macaques and baboons. Deliveries of quick-frozen or fixed specimens are made on a scheduled basis. Viable specimens in culture media are prepared for shipment in less than an hour and delivered to most laboratories in the U.S. within 24 hours. More specialized preparations are supplied on request. A clinical and experimental history of the donor animal accompanies each specimen.

This Tissue Banking and Distribution Program is partially supported by the Division of Research Resources (DRR).

For more information, call or write:

Ms. Judy Johnson
Tissue Program Coordinator
Regional Primate Research Centers SJ-50
University of Washington
Seattle, Washington 98195

Telephone: (206) 543-6999

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

P.T. 36; K.W. 1002024, 1004019, 1014001

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: February 15, 1985

I. BACKGROUND

The Division of Research Resources (DRR) is continuing its competitive Biomedical Research Support (BRS) Shared Instrumentation Grant Program initiated in Fiscal Year 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of NIH-supported biomedical investigators, research instruments which can only be justified on a shared-use basis and for which meritorious research projects are described.

Eligible institutions may submit more than one application for different instrumentation in the Fiscal Year 1986 review cycle.

II. RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other NIH mechanisms, such as the regular research, program project and center grant programs, or the Biomedical Research Support (BRS) Grant Program. Proposals for the development of new instrumentation will not be considered.

III. ELIGIBILITY

The BRS Shared Instrumentation Grant Program is a subprogram of the BRS Grant Program of DRR. Awards are made under the authority of the BRS program and are made to institutions only, not to individuals. Therefore, eligibility is limited to institutions which receive a BRS grant award. Awards are contingent on the availability of funds.

This program is described in the Catalog of Federal Domestic Assistance No. 13-337, Biomedical Research Support. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

IV. MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in both basic and clinical research. Applications are limited to instruments that cost at least \$100,000 per instrument or system. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or purely instructional equipment. Proposals for "stand alone" computer systems will only be considered if the instrument is solely dedicated to the research needs of a broad community of NIH-supported investigators.

Awards will be made for the direct costs of acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is \$300,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. Cost sharing is not required. If the amount of funds requested does not cover the total cost of the instrument, an award will not be made unless the remainder of the funding is assured. Description of the proposed co-funding must be presented with the application. Assurance of co-funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award.

A major user group of three or more investigators should be identified. Each major user must have NIH peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple NIH research awards and demonstrate that these projects will require at least 75% of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. NIH extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the advisory committee. These users need not be NIH awardees but priority should be given to NIH supported scientists engaged in biomedical research.

A progress report will be required which describes the use of the instrument, listing all users, and indicating the value of the instrumentation to the research of the major users and to the institution as a whole.

V. ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. The Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation

of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

VI. REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants (DRG) for scientific and technical merit and by the National Advisory Research Resources Council of the DRR for program considerations. Funding decisions are the responsibility of the DRR and will not be made prior to November 15, 1985.

Criteria for review of applications include the following:

1. The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.
2. The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.
3. The adequacy of the organizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.
4. The institution's commitment for continued support of the utilization and maintenance of the instrument.
5. The benefit of the proposed instrument to the overall research community it will serve.

VII. METHOD OF APPLYING

Copies of a more detailed announcement are being mailed to the business offices of all institutions currently receiving BRS grants. Interested investigators should obtain the complete announcement prior to preparing an application.

Applications must be received by February 15, 1985. Applications received after this date will not be accepted for review in this competition. The original and four copies should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Inquiries and two copies of the application should be addressed to:

Biomedical Research Support Program
Division of Research Resources
National Institutes of Health
Building 31 - Room 5B23
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 496-6743

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-HD-01CONSEQUENCES OF INFERTILITY AND FERTILITY-RELATED PROBLEMS

P.T. 34; K.W. 0413002, 0404000, 1201070, 1200320, 0701014, 0413001

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: March 15, 1985

SCIENTIFIC PROGRAM OBJECTIVES

The Demographic and Behavioral Sciences Branch (DBSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), supports research on the antecedents and consequences of fertility and fertility regulation. The RFA, for which this is a notice of availability, invites scientists to study the psychosocial consequences of infertility and fertility-related problems and the subsequent impact of these consequences on fertility-related behavior. Research proposals are needed to cover the wide range of psychological, social, economic, and behavioral consequences to couples who experience any of the following: (a) infertility, (b) problems in conceiving, (c) problem pregnancies (such as spontaneous abortions, fetal death, medical complications of pregnancy), (d) problems in the birth process (such as difficult presentation, heavy bleeding, prolonged labor), (e) premature birth, (f) infant morbidity, (g) birth anomalies, and (h) neonatal and infant mortality.

The psychological, social, economic and behavioral consequences of experiencing one or more of these problems need to be studied, including the following: (a) changes in the spacing, timing and number of births expected, desired and attempted; (b) changes in contraceptive and sexual practices; (c) changes in marital relationships; (d) changes in wage market behavior on the part of either the man or the woman (or both); (e) adoption, fostering and child care activities; (f) psychosocial problems; (g) changes in interaction between family members and between family members and significant others; (h) subsequent behavior concerned with attempts to conceive (including medical care sought to aid conception, such as surgery, medication, artificial insemination and in vitro fertilization). To the extent feasible, investigators should control for such intervening variables as the health of the couple and demographic factors related to fertility.

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA).

Copies of the complete RFA may be obtained from:

Gloria Kamenske, Ph.D.
Demographic and Behavioral Sciences Branch
National Institute of Child Health
and Human Development
Landow Building - Room 7C25
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-02

THE PHYSIOLOGY OF LACTATION AND THE BIOLOGY OF HUMAN MILK

P.T. 34; K.W. 0701027, 1002034, 1201070, 0202022, 1200780, 0404019, 0701046

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Letter of Intent Receipt Date: January 15, 1985

Application Receipt Date: March 1, 1985

I. BACKGROUND

The Endocrinology, Growth and Nutrition Branch of the National Institute of Child Health and Human Development (NICHD) invites investigator-initiated research grant applications for studies on the physiology of lactation and the biology of human colostrum and milk. These research areas have been identified as high priority by the Surgeon General's Workshop on Breastfeeding and Human Lactation, June 11-12, 1984, as well as by an NICHD-sponsored conference entitled "Methods in Human Lactation," August 22-25, 1984. It was the consensus of these meetings that research on the physiology of lactation and on the function of components found in human colostrum and milk has lagged behind other aspects of human physiology investigations. The importance of research in these areas is further emphasized by the growing number of reports in the scientific literature about functional properties of human milk that were previously unknown. A new appreciation is emerging of these unique biological fluids and the processes that occur in the mammary gland to produce them.

A concerted effort is now needed to explore the physiological processes occurring in the breast from the time of conception through lactation and weaning in order to understand the process of development and function of lactating tissue. Along with this, the functional properties of colostrum and human milk need to be evaluated in the context of the roles played by these properties in infant development.

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The influence of the entire maternal circumstance (such as nutritional status, environment, stress, lifestyle and health) on these functional properties of milk also needs to be addressed.

II. OBJECTIVE AND SCOPE

It is expected that individual applications responding to this RFA will relate to some aspect of the following areas. These descriptions are necessarily brief and are not intended to cover all aspects that might be appropriate to each area. They are general in nature in order to allow the investigator latitude in study design.

Lactation Physiology and Maternal Factors

- o Studies on the events associated with metabolic and functional changes occurring in the breast that lead to lactation.
- o Studies on the function of the breast during milk secretion and weaning.
- o The role of maternal nutrition and metabolism on the development and maintenance of lactation.
- o The effects of commonly used pharmacologic agents, environmental agents, smoking and alcohol consumption on lactation.

Biology of Human Colostrum and Milk

- o Studies on the organizational and functional properties of human colostrum and milk. These include:
 - Studies on the functional properties associated with subcellular organized particles.
 - The function and organization of immune components in milk and their relationship to the establishment of the intestinal immune system of the infant.
 - The role and function of enzymes and other proteins in milk.
 - The functional properties of the non-protein nitrogen component of human milk.
 - The organization and function of the lipid fraction of human milk.
- o Studies on the effects of commonly used pharmacologic agents, environmental agents, smoking and alcohol consumption on human colostrum and milk and on infant outcome.
- o Studies on the effects of maternal factors on the composition of colostrum and milk.

III. STAFF CONTACT

For further information and a copy of the RFA, contact:

Thorsten A. Fjellstedt, Ph.D.
Health Scientist Administrator
Endocrinology, Growth and Nutrition Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development

Telephone: (301) 496-5575

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-05

CANCER CONTROL SMALL GRANTS RESEARCH PROGRAM

P.T. 34, 12; K.W. 1002014, 0701013, 1200270, 0403004

NATIONAL CANCER INSTITUTE

Application Receipt Date: February 12, 1985

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites Small Grants Research applications from interested investigators who meet the eligibility criteria noted below. This RFA is a reissuance of RFA 84-CA-07.

I. RESEARCH GOALS AND SCOPE

A Cancer Control Small Grants Research Award is designed to encourage scientists from a variety of academic disciplines to apply their skills to scientific investigations in the field of human cancer control intervention research.

Definition and Phases of Cancer Control

Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results.

Cancer control research studies are classified into one of five phases which represent the orderly progression noted in the above definition: (I) hypothesis development; (II) methods development and testing; (III) controlled intervention trials to establish cause and effect relationships; (IV) research in defined, human populations; and (V) demonstration and implementation studies. The Division is primarily interested in research on cancer control interventions in Phases II through V.

Cancer Control Program areas appropriate for research grants include human intervention research in prevention (chemoprevention, diet and nutrition, occupation and early detection), community oncology (improving application of patient management and continuing care research advances in community settings), and health promotion sciences (modifying personal, social and lifestyle and health care system factors which contribute to cancer prevention and control).

These cancer control studies may also include applied epidemiology studies, which attempt to use epidemiologic methods to determine the association between exposure to an intervention and its impact on disease; epidemiologic, planning and survey studies aimed at developing cancer control interventions could also be included.

Studies to determine the efficacy of chemotherapy, surgery, radiotherapy, and other primary treatment interventions are not considered cancer control research under this RFA.

II. ELIGIBILITY

Investigators are eligible to apply for a small grant to support research on a cancer control topic if they are interested in conducting exploratory studies in cancer control research and have never received NCI cancer control funding. This includes established researchers from other disciplines, new investigators, and investigators currently enrolled in an accredited doctoral degree program; however, it excludes individuals who have ever been a Principal (or Co-Principal) investigator on an NCI funded cancer control grant or contract, or a paid staff member on an NCI funded grant or contract for more than one year.

If the research will constitute a doctoral dissertation, a written statement from the applicant's dissertation chairperson or equivalent academic supervisor that the project proposal has his/her approval must accompany the application; if the study is selected for support under this program, a statement of approval of the full dissertation committee is required before funding will be made.

III. MECHANISMS OF SUPPORT

The mechanism of support is the NIH grant-in-aid. Total costs (direct plus indirect costs) must not exceed \$35,000. The duration of support is one year but may be longer (up to two years) if the funding limits noted above are not exceeded. The direct costs for dissertation research should not exceed \$15,000.

IV. INQUIRIES

Copies of the complete RFA and additional information may be obtained from:

Dr. Carlos E. Caban
Program Director
Cancer Control Applications Branch
Blair Building - Room 4A01
Division of Cancer Prevention and Control
National Cancer Institute
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

Prospective applicants are strongly encouraged to discuss their ideas with the Program Director to determine whether they fit within the definition and program guidelines of cancer control. Applications which, in the opinion of NCI staff, do not fit will be returned without review.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS (RFA)

PROTECTION OF THE IMMATURE MYOCARDIUM

85-HL-16H

P.T. 34; K.W. 1200230, 1200240, 1002034, 1200780, 1002004, 0701038, 1201020, 1201260

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: March 15, 1985

The Cardiac Diseases Branch, Division of Heart and Vascular Diseases, National Heart, Lung and Blood Institute (NHLBI) announces the availability of a request for applications (RFA) on the above program. The purpose of this special grant program is to stimulate further fundamental research regarding the protection of the immature heart during periods of hypoxia, ischemia, and reperfusion. Studies which should lead to a greater understanding of the vulnerability of the immature heart might include: developmental changes in myocardial function and ionic exchange; developmental changes in myocardial metabolism; effects of myocardial ischemia and reperfusion on cardiac function and structure in the neonate; and mechanism of reperfusion injury.

This announcement may be of particular interest to investigators in such disciplines as biochemistry, cellular physiology and biology, pharmacology, and pediatric cardiology and surgery.

The due date for the receipt of applications will be March 15, 1984. Requests for copies of the RFA should be addressed to:

Zena McCallum
Cardiac Diseases Branch
National Heart, Lung, and Blood Institute
Federal Building - Room 3C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1081

ANNOUNCEMENT

BLOOD TRANSFUSION AND CYTOMEGALOVIRUS INFECTION

P.T. 34; K.W. 1200200, 1200670, 1002045, 1002023

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI) encourages grant applications to study the role of blood transfusion in the transmission of cytomegalovirus (CMV) infection. CMV is a member of the herpes virus group that may infect humans by many natural or iatrogenic routes. A large proportion of the population has been infected with CMV as evidenced by the presence of antibody; however, infection is usually mild or clinically inapparent. In certain patient populations, such as those undergoing immunosuppressive therapy, the clinical outcome of CMV infection is usually less favorable, often resulting in death.

Data are insufficient to define the magnitude of the problem of CMV and the extent of the involvement of blood transfusion in transmitting the disease in various patient populations. If present estimates of posttransfusion CMV infections are accurate, this may be a major problem in many different kinds of immunosuppressed patients. There is an urgent need to develop methods to identify infectious donors and methods to render blood and blood components noninfectious. Such methods should substantially improve survival in many groups of susceptible patients. Investigators with expertise in virology, transfusion medicine, transplantation, and neonatology will be supported by this program. Studies in animal models and in appropriate human patient populations are envisioned.

Specific objectives of this solicitation are to: (1) define the populations of children and adults susceptible to CMV infection from blood transfusions; (2) determine the risk of blood transfusion-transmitted CMV infection; (3) identify the component(s) of blood that may transmit CMV; (4) develop methods to render blood and blood products noninfectious, and (5) develop an assay to identify infectious donors. Applicants are encouraged to pursue one or more of these objectives.

Applicants should use the regular research grant application (PHS 398). There are three receipt dates each year for new applications: March 1, July 1, and November 1. If applications are not available at the institution's business office or central application control office, an individual copy may be requested by writing to Division of Research Grants (DRG) NIH. The original and six copies of the application should be mailed to:

This program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

All applications will be assigned by the DRG for review according to the NIH process for regular research grant applications. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Applications recommended for approval will compete for available funds with all other approved applications assigned to the NHLBI.

Inquiries should be directed to:

Dr. Luiz H. Barbosa
Blood Resources Branch
Division of Blood Diseases
and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1537

ANNOUNCEMENTMINORITY INSTITUTIONAL RESEARCH TRAINING GRANT

P.T. 44; K.W. 1200240, 1200230, 1201210, 1200560, 0403013

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The National Heart, Lung, and Blood Institute (NHLBI) announces a new program to train graduate students in minority schools for research careers in areas related to cardiovascular, pulmonary or hematologic diseases. The support mechanism will be the NIH research training grant. Copies of the program guidelines are currently available from staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions, each of which will cooperate with a research center that has a well-established cardiovascular, pulmonary, or blood research and research training program. Each trainee will be placed with a mentor who is an accomplished investigator at the cooperating research center and who will assist the advisor at the minority institution in the trainee's development and research plan.

Guidelines for this program may be obtained from any of the following:

George Hayden, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan M. Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A12
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.837, 13.838 and 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 8-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Luiz Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1537

ANNOUNCEMENTMINORITY SCHOOL FACULTY DEVELOPMENT AWARD

P.T. 14, 34; K.W. 0403013, 1200180

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1985

The National Heart, Lung, and Blood Institute (NHLBI) announces a new program to encourage the development of faculty investigators at minority schools in areas relevant to cardiovascular, pulmonary, blood diseases, and blood resources. Copies of the program guidelines are currently available from the staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions on behalf of awardees, each of which will work with a mentor at a nearby (within 100 miles) research training center, who is recognized as an accomplished investigator in the research area proposed and who will provide guidance for the awardee's development and research plan.

Guidelines for this program may be obtained from any of the following:

George Hayden, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan Wolle, Ph.D.
Division of Lung Disease
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A12
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.837, 13.838, and 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Luiz Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone (301) 496-1537

ANNOUNCEMENT

DEVELOPMENT OF GENETIC HYPERTENSIVE ANIMAL MODELS

P.T. 34; K.W. 1200600, 1200410, 1002019, 1002002

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: March 1, July 1 and November 1

The National Heart, Lung, and Blood Institute (NHLBI) supports numerous basic research projects dealing with many of the multiple facets of essential hypertension. Essential hypertension is believed to have a genetic component, which is polygenic in nature. Therefore, the phenotypic expressions (genetic traits) are many and varied. However, despite this genetic multiplicity most of the basic research has been done with one genetic hypertensive model, the Okamoto spontaneously hypertensive rat (SHR). This model appears relevant to human essential hypertension and it is readily available. Other genetic hypertensive models do exist (e.g. the New Zealand Rat), but they are far less accessible than the SHR. Because of these circumstances, virtually all scientific advisory groups that have assessed the research needs of the hypertension field have at one time or another recommended the development of new hypertensive models including genetic models.

This program announcement is to encourage the development of new genetic animal models of hypertension. To develop a model it is imperative that a breeder work with an investigator so that the finished product reflects the research need and is marketable. This announcement offers support for the development phase in the hope that once a genetic hypertensive model is established, private enterprise will take over and make it accessible to all investigators. With appropriate attention to detail, both the research value of the model and its marketability can be enhanced. The model should (1) facilitate research; (2) be healthy; and (3) be cost-effective. All animal species will be considered. This announcement pertains to the de novo development of animal models, as well as to refinement of animal models whose development is already underway but not yet completed. The input of a geneticist is desirable.

This announcement is addressed to animal breeders and hypertension investigators through the regular research grant program and also through the Small Business Innovative Research (SBIR) program.

This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

APPLICATION SUBMISSION AND REVIEW

Regular Research Grant Program

Receipt dates for new applications are the regular application receipt dates of March 1, July 1, and November 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form (PHS 398), which is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and put **"Development of Genetic Hypertensive Animal Models"** under item 2 of page 1 of the grant application. The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Armando Sandoval
Hypertension and Kidney Diseases Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C08
Bethesda, Maryland 20205

Telephone: (301) 496-1857

Small Business Innovative Research (SBIR) Program

Anyone interested in responding to this announcement through the SBIR program should request the Omnibus Solicitation for SBIR from:

Office of Grants Inquiries
Division of Research Grants
Westwood Building - Room 449
Bethesda, Maryland 20205

The Omnibus Solicitation contains information about the SBIR program, an application form and instructions how to apply. Questions regarding the genetic hypertensive model program should be addressed to Mr. Sandoval whose address and phone number appear above.

ANNOUNCEMENT

ACCESS TO BIONET FOR SEQUENCE ANALYSIS

P.T. 36; K.W. 1004001, 1002008, 1004007, 1004011, 1201190

BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM

DIVISION OF RESEARCH RESOURCES

I. BACKGROUND INFORMATION

The BIONET(tm) Resource is a central computer facility serving the computational needs, for both research and communication, of the molecular biology community. The Resource is funded through a cooperative agreement between the Biomedical Research Technology Program of the Division of Research Resources (DRR) and the IntelliGenetics Division of IntelliCorp, Palo Alto, California, which is providing the computer facilities, core software and support. Responsibility for overseeing the Resource rests with a National Advisory Committee (NAC).

II. BIONET GOALS AND ENVIRONMENT

The BIONET Resource has three goals:

1. To provide computational assistance in data analysis and problem solving for molecular biologists and researchers in related fields.
2. To serve as a focus for development and sharing of new software tools.
3. To promote collaboration and rapid sharing of information among a national community of scientists.

The computer hardware of the Resource includes:

- * An interactive timesharing computer (Digital Equipment Corporation 2060) and associated peripheral equipment (tape drives, disks).
- * Telecommunication access to the computer, locally via dial-in, remotely via a nationwide network.

The computer software is divided into four categories:

- * The Core Library, consisting of nine programs from IntelliGenetics, for manipulating and analyzing nucleic acid and protein sequence data, plus additional programs selected by the NAC.
- * The Database Library, containing existing databases of nucleic acid and protein sequences, including GenBank(tm), the European Molecular Biology Laboratory (EMBL) database, the National Biomedical Research Foundation (NBRF) library of protein sequences, and VectorBank(tm).

- * The System and Programming Support Library, providing tools for program development, to include programming languages (Fortran, C, Pascal, MAINSAIL, MACLISP, and Interlisp) and system utility programs (MLAB, for mathematical modeling, EMACS and TVEDIT for text editing, and SCRIBE for document preparation). Facilities for electronic mail and electronic bulletin boards will also be provided to foster rapid communication and collaboration. KERMIT will be available for file transfer to and from the Resource.
- * The Contributed Library, for programs contributed and being developed by the BIONET community. Mature versions of such programs will be moved to the Core Library at the discretion of the NAC.

The Resource staff will provide this support to the BIONET community:

- * User consultation by telephone and on-line communication.
- * Documentation of programs in the Core Library.
- * Regional training sessions in use of the software.
- * Assistance in moving programs into the Contributed and Core libraries.

III. GUIDELINES FOR ACCESS

Users of the Resource are divided into Class I (service) and Class II (collaborative) users. Class I users will have access to the programs in the Core, Database, and Contributed Libraries, and to the electronic mail and bulletin board facilities. They will use these resources to support their current research, and to contribute information to the Resource community. Class II users will contribute programs to or collaborate in developing new programs for the BIONET Resource and will have access to all four categories (above) of system resources to aid in this effort.

The NAC has set these criteria for eligibility:

Class I--the BIONET Resource will admit pro forma, researchers from academic and non-profit institutions in the U.S., who can demonstrate that they are supported by governmental, philanthropic, or unrestricted institutional funds and that their research can be assisted by the Resource facilities. The BIONET staff will consider on a case-by-case basis applications from investigators in foreign countries or from investigators funded from proprietary or restricted sources, and make recommendations to the NAC, which will make final decisions on all access to the Resource.

Class II--These users must meet the admission requirements for Class I access. In addition, they must indicate that they will participate in developing the Resource, by providing new programs to the BIONET community that help achieve the goals described above. BIONET will restrict the number of Class II users because of the anticipated heavy demands each will place on the facilities. Use of the Resource will be carefully monitored by the staff and the NAC. There will be no initial charge for access to the BIONET computer. A fee-for-service may be required in the future. Researchers will have sufficient warning of fees to include requests for additional funds in their research grant proposals.

The BIONET Resource provides only a computer facility and associated services. It does not provide research equipment. The Resource has a small fund for fostering collaborations and will use this fund, when no other means are available, to support an effort that will advance the goals of the Resource.

IV. APPLICATION PROCEDURES

An application form can be obtained from:

BIONET Applications
c/o BIONET Manager
IntelliGenetics, Inc.
124 University Avenue
Palo Alto, California 94301

A limited fund is available to support the production and distribution of documentation. Approved applicants will receive, free of charge, introductory material on access to BIONET, use of electronic mail and bulletin boards, and brief descriptions of the use of each of the programs in the Core Library. A complete program reference manual is available, at cost, from BIONET for \$35.

V. STAFF CONTACT

The NIH contact for further information is:

Dr. Charles L. Coulter
Head, Biological Structure Section
Biomedical Research Technology Program
Division of Research Resources
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5411

ANNOUNCEMENTTHE OLDEST OLD

P.T. 34; K.W. 0404002, 0701013, 0413001, 0408006, 0701016, 0701010, 1201230

THE NATIONAL INSTITUTE ON AGING

I. BACKGROUND AND GOALS

The National Institute on Aging (NIA) invites qualified researchers to submit new and supplemental applications for research projects which focus on the oldest old--those over age 85. Although the over age 85 population is still small in absolute numbers (about 2.6 million), it is forecast to be the fastest growing segment of the population for the period 1980-1990. For the last several decades the over age 85 population has been growing at almost three times the rate of that of all persons over age 65. While comprising only one percent of the total U.S. population today, this segment is projected to rise to 1.9 percent (5 million) by the year 2000, and 5.2 percent by 2050 (16 million). Assumptions about the future direction of the mortality rates of this age group powerfully influence these projections.

The oldest old are very substantial users of health care and other services. While about 6 percent of those aged 75-84 are institutionalized, the rate for those over age 85 is about 23 percent. The 1979 National Health Interview Survey data showed that in just the non-institutionalized elderly, the need for help from another person in one or more activities of daily living increased substantially. Seven percent of those aged 65-74 required help as compared to 16 percent for those aged 75-84, and to over 40 percent for those over 85. This gradient was even steeper in the female population, which greatly outnumbers the male population at older ages. If the current utilization rates for health and other services for this age group are extrapolated simply as a function of the projected growth of the oldest old population, then the implications for society are considerable.

The Federal Government provides, by some estimates, \$51 billion in major benefits to those 80 and over. Yet, at almost all levels, from the demographic to the physiologic, less is known about this age group than about any other. For example, federal statistics rarely provide detailed information on those over age 85. Our lack of knowledge about the oldest old results from a number of factors. Until recently their absolute numbers have been small, the available data have often been perceived to be of low quality, and this age group has been considered difficult to study.

This program is described in the Catalog of Federal Domestic Assistance No.13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66, and Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

This announcement of NIA's special initiative on the Oldest Old supplements, but does not replace, such prior announcements as "Social and Behavioral Research" and "Health and Effective Functioning in the Middle and Later Years".^{1/} This initiative is being sponsored jointly by the Behavioral Sciences Research and Biomedical Research and Clinical Medicine Programs of the NIA, and is coordinated with related programs in the National Institute of Mental Health and the National Institute of Child Health and Human Development.

II. SPECIFIC OBJECTIVES

This announcement indicates the wide array of knowledge needed, starting with the urgently needed assessment of the quality of the existing data, and the development of improved sources of information and methodologies for studying the oldest old. Also needed are descriptive and analytic studies. Among the broad topics of concern are:

A. Assessment of Existing Data and Methodological Innovations

1. Studies assessing the quality of existing data, and methodological innovations to improve data quality; e.g.:
 - o Studies which improve the representativeness and reliability of data for those over 85, including studies to sharpen current definitions of the household by delineating new types of living arrangements. Improved methods for interviewing and obtaining valid and reliable data for persons with limitations of hearing, vision, memory or comprehension. Improved methods of collecting data in institutions; analyses of the differences in the quality of data collected from the individual versus that from administrative records or from proxy respondents. Studies leading to improved record collecting, cause-of-death reporting, and an increased autopsy rate. Studies which improve the measurement of the various forms of functional ability.
 - o Studies to improve the ability to project and forecast changes in life expectancy and active life expectancy. Development of improved methods for assigning confidence bands to projection.

B. General Characteristics of the Oldest Old

1. Socio-demographic studies within both the United States and other industrialized nations such as:
 - o Distribution and projections by, e.g., sex, race, education, income, residence, and living arrangements. Investigations of migration. Analyses of the composition and proximity of surviving kin.

^{1/} See NIH Guide for Grants and Contracts, Vol. 12, No. 6, June 17, 1983, pp.5-15, Vol. 10, No. 10, September 4, 1981.

- o Analyses of sociodemographic historical trends in the oldest old, and the impact of cohort succession (e.g., in the percent foreign born and of increasing levels of education, etc.) on their characteristics.
 - o Economic issues such as the distribution of income and wealth in sub-populations, and the conditions under which financial reserves become exhausted; the impact of anticipated institutionalization on saving and consumption; the transmission of assets and patterns of exchange between generations; illiquidity and the implications of reverse mortgages; the assessment of income adequacy measures; relationships between financial status and sense of financial well-being; conditions of daily life of those below, or close to, the poverty line; the economic determinants of living arrangements.
2. Descriptions and analyses of patterns of functioning, morbidity, and disease-specific causes of death. For example:
- o Studies of stability and decline in such abilities as memory and problem solving; individual reactions to reduced competency; the epidemiology of sensory and communication problems.
 - o Clinical, pathologic, and epidemiological data on the prevalence, course, morbidity, and mortality of diseases.
 - o Physiologic factors (e.g., metabolic, endocrine, immune, skeletal-muscular, sensory, and cardiovascular) which increase or diminish risk for decrements in functioning, specific diseases, and mortality from disease.
 - o The interaction of multiple disease processes to determine the effects of co-existent diseases on functioning, morbidity, mortality, and implications for intervention and therapy.
 - o Studies of variation in mortality, morbidity, and patterns of functioning among the population sub-groups of the oldest old within the U.S. and other nations. Studies of the reported "mortality cross-over" phenomenon between black elderly and their white counterparts. Factors which may be associated with differential survival, health, and functioning at the oldest ages, including lifestyle, health behaviors, medical and self care, and genetic and familial background.
- C. Interactions with the Society Including Care Systems
1. Studies of the care systems of the oldest old in areas such as:
- o The impact of the changing family and increasing participation of women in the labor force on the provision of care for future cohorts of the oldest old. Social and economic effects on families caring for the frail oldest old. The impact of health care reimbursement policies on relationships between formal and informal care systems. Assessment of the resources which allow

Interest in some of the above areas is shared by the National Institute of Mental Health (NIMH). Applications will be assigned according to standing referral guidelines. Information on NIMH program interests can be obtained from;

Center for Studies of the Mental Health
of the Aging
Parklawn Building - Room 11C-03
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1185.

The review criteria are the traditional considerations underlying scientific merit.

Investigators are encouraged to discuss their projects and the range of available grant mechanisms with NIA staff in advance of formal submission. This can be done through a telephone conversation or brief (4-5 page) research prospectus. Applicants should use the regular research project application form (PHS 398), which is available at the applicant's institutional Application Control Office or from:

Office of Grants Inquiries
Division of Research Grants (DRG)
National Institutes of Health

Telephone: (301) 496-7441

In order to expedite the routing of applications within NIH, please (1) check the box on the application face sheet indicating that your proposal is in response to this announcement and print (next to the checked box) "NIA: THE OLDEST OLD" and (2) enclose a cover letter repeating that your application is in response to this announcement.

Mail the cover letter and the completed application (with 6 copies) to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Receipt dates for Research Project Grant and New Investigator Award applications are: March 1, July 1, and November 1; for others, including Postdoctoral Fellow and Program Project applications: February 1, June 1, October 1.

Address requests for additional information (e.g., sources of data) research prospectuses, and/or letters of intent to:

functioning outside of long-term care settings.

- o Studies of the last year of life including interactions among patients, family, care providers, nursing homes, and the legal system, and implications for costs and patient well-being.
2. Factors affecting institutionalization and use of services, e.g.:
- o Dementia and other cognitive impairments; osteoarthritis and other causes of impaired mobility; falls and other injuries; and urinary and fecal incontinence.
 - o Living arrangements and the physical characteristics of housing units, including innovations designed to keep the frail in the community, and the availability of support. Comparative analyses among jurisdictions, social, ethnic, and racial groups, or other nations with different rates of institutionalization.
3. Interactions between the oldest old population and society, e.g.:
- o Forecasting and modeling the impact of the rapid growth of the oldest old population on e.g., the economy, the social security system, the insurance industry, the distribution of income, the health care system, housing, the political system, intergenerational solidarity; and the family structure. Dynamics of resource allocation among age strata. Comparisons of the adaptation of institutions to the growth of the over 85 population across industrialized nations experiencing different rates of structural aging. The impact of social trends.
 - o Special socio-legal problems of this age category; comparison among jurisdictions in the United States of the impact of laws (and their changes) affecting the oldest old and their families; studies of their interactions with the legal system, including analyses of conservatorships, the right of patients to refuse or terminate care and the reactions of institutions to such requests.

III. METHODOLOGY

Research applications need not be limited to any particular methodology of data collection or analysis. Designs will frequently need to include comparisons with age groups below age 85. Designs may include demographic, epidemiological, econometric, and clinical studies with cross-sectional, longitudinal, or cohort designs. Cross-national (and multi-state) comparisons are strongly encouraged. Secondary analysis of existing data is encouraged, although collection of new data will be necessary to meet particular objectives. Where new data are collected, very careful consideration should be given to human subject concerns (see NIH Guide for Grants and Contracts, Vol. 10, No. 4, March 6, 1981).

IV. APPLICATION SUBMISSION AND REVIEW

Applications received in response to this announcement will be assigned to regular peer review groups and will be considered in accordance with NIH guidelines.

For all topics other than biomedical:

National Institute on Aging
Behavioral Sciences Research
Attention: "Oldest Old"
Building 31C - Room 4C32
Bethesda, Maryland 20205

Telephone: (301) 496-3136

For biomedical topics:

National Institute on Aging
Biomedical Research and
Clinical Medicine
Attention: "Oldest Old"
Building 31C - Room 5C21
Bethesda, Maryland 20205

Telephone: (301) 496-1033

ANNOUNCEMENT

EFFECT OF ENVIRONMENTAL AGENTS ON THE ENDOCRINE SYSTEM

P.T. 34; K.W. 1007003, 1200435, 1200090

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Dates: March 1, July 1, November 1

I. BACKGROUND

Although the Division of Diabetes, Endocrinology and Metabolic Diseases (DEMD), National Institute of Arthritis, Diabetes and Digestive and Kidney Disease (NIADDK) supports a major program of basic and clinical research in Endocrinology and the National Institute of Environmental Health Sciences (NIEHS) is the major Federal funding agency for support of basic research in Environmental Health Sciences, neither Institute has previously identified the interaction of chemicals of environmental concern with the endocrine system or the effect of such interaction as an area of special interest.

II. RESEARCH GOALS AND SCOPE

This announcement is issued to stimulate interest in and to increase research activity in environmental endocrinology (i.e., the interaction with and effect of environmental chemicals on the endocrine glands, hormones and receptors). Collaborative research efforts between Endocrinologists and Toxicologists or scientists in closely related disciplines are especially encouraged; applications from individual scientists are also solicited.

Research interests include but are not limited to studies of: 1) the direct and indirect effect of environmental agents on the endocrine and neuroendocrine system, 2) the blocking of hormone release by environmental agents, 3) hormonal actions of environmental agents, mycotoxins and other environmental pollutants, 4) the effect or role of hormones on the toxicity of chemicals, and 5) development and standardization of more sensitive tests for detecting early damage by environmental agents.

This program is described in the Catalog of Federal Domestic Assistance No. 13.112, Characterization of Environmental Health Hazards; 13.113, Biological Response to Environmental Health Hazards; 13.114, Applied Toxicological Research and Testing; 13.115, Biometry and Risk Estimation; and 13.847, Diabetes, Endocrinology and Metabolism. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

III. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the individual research grant - Research Project Grant and New Investigator Research Grant, as applicable.

IV. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications, i.e., March 1, July 1, and November 1. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of March 1, 1985.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. It is likely that most applications submitted in response to this announcement would receive dual Institute assignments. In general, applications in which the major research interest is on the effect of the environmental agents will be assigned to NIEHS. Applications which focus on the endocrine system and the chemical agents used to elucidate endocrine function will be assigned to NIADDK. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contract offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in Item 2 on the face page of the application and enter the title "Effects of Environmental Agents on the Endocrine System."

The original and six (6) copies of the application should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries related to Environmental studies should be directed to:

Dr. Edward Gardner, Jr.
Program Director
Regular Research Grants Program
National Institute of Environmental
Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-7724

Inquiries related to Endocrinology Studies should be addressed to:

Dr. Robert A. Tolman
Endocrinology Research Program Director
NIH, NIADDK, DEMD
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7504

ANNOUNCEMENT

RESEARCH ON MENTAL ILLNESS IN NURSING HOMES

P.T. 34; K.W. 0701029, 0701033, 1201160, 0404000, 1201175, 1201170, 0701038, 0701026

NATIONAL INSTITUTE OF MENTAL HEALTH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Application Receipt Dates: March 1, July 1, November 1, 1985

The National Institute of Mental Health (NIMH) through the Center for the Studies of the Mental Health of the Aging (CSMHA) seeks applications for individual research projects which will increase knowledge and improve research methodology on emotional, social, behavioral, and mental disorders of residents in nursing homes; will generate information regarding the interplay of biological, behavioral, genetic, and social processes underlying these disorders and the maintenance of mental health among nursing home residents; and will increase knowledge of mental health services and practices.

The proposed research may employ theoretical, laboratory, clinical, methodological, and field studies, and may involve normal elderly subjects as well as residents in nursing homes.

I. TOPICS OF RESEARCH INTEREST

For purposes of this announcement, specific research topics of interest include but are not limited to:

- o Clinical research in major mental disorders in nursing homes.
 - Interface of physical and mental illness in the nursing home, and the impact of mental illness on provision of care in the home.
 - Basic and clinical research on the nature, description, classification, etiology, clinical course, and prognosis of mental disorders and related behavioral disorders in nursing homes, i.e., dementing disorders, depression, anxiety, paranoia, schizophrenia, personality disorders, character disorders, etc., and how these disorders are identified, assessed, and/or treated in the context of particular types of nursing homes.

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research Grants. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- Identification and analysis of excess disability--where the magnitude of functional disturbance is far greater than might be reasonably accounted for by the presence of physical illness or cerebral pathology itself.
- Development of valid behavioral and functional assessment instruments which can be used by nursing personnel for purposes of diagnosing and monitoring the course and outcome of illness.
- Studies of treatment resistant syndromes in nursing homes.
- Identification of psychological, biological, and environmental precipitants and concomitants of disorientation in nursing home residents.
- o Somatic and nonsomatic treatment and management of mental disorder and behavioral problems in nursing homes.
 - Effects of behavioral psychotherapies on cognitively and affectively impaired elderly in the nursing homes.
 - Clinical pharmacokinetical studies on representative treatment groups in the nursing home to define more precisely dosage requirements and subject selection characteristics for psychopharmacological treatments.
 - Studies on the iatrogenic role of pharmacological agents associated with such outcomes as confusion, memory impairment, cognitive dysfunction, clouding of consciousness, gait disturbances, etc.
 - Impact of specific forms of social support and interpersonal relationships on cognitive decline, levels of self-esteem, and general emotional and physical health.
 - Methodologies for assessing specific types of interventions for preventing and/or ameliorating emotional and cognitive impairment and dysfunctional behaviors among residents of nursing homes.
 - Identification of effective strategies/interventions for preventing or reducing, over time, mental confusion and wandering.
- o
 - Prevention of psychopathology and promotion of mental health among the nursing home residents and their families.
 - Ways to enhance self-esteem and autonomous or interdependent functioning, self-care, and mutual support in nursing home residents.
 - Identification of the most effective coping strategies and/or intervention used by the caregivers (institutional and family), and kinds of information, training/counseling, and social support which reduce stress and reinforce the increased coping abilities of families of Alzheimer's disease victims.

- Strategies for prevention of dysfunctional behaviors.
- o Mental health service design and delivery research in nursing homes.
 - Strategies for the development and analysis of linkages between nursing homes, community mental health centers, State hospitals, and private psychiatric hospitals.
 - Use of resource utilization groups (RUG) in planning and evaluation of care of the mentally ill elderly (RUG in long-term care is the equivalent to diagnostic related groups (DRG) in acute hospital settings).
 - Studies in occupational mental health, staff morale, and staff burn-out.
- o Mental health and mental illness as risk factors for institutionalization and discharge.
 - Followup on admission to determine the probability of residents with particular symptoms, syndromes, and psychosocial characteristics for release, retention, or death.
 - Relationship of physical, psychiatric, emotional, and developmental disorders, social support, and family dynamics in the nursing home placement process and in treatment management selection.

II. APPLICATION

Interest in some of the research topics is shared by the National Institute on Aging (NIA). Applications will be assigned according to the standard referral guidelines. State and local Government agencies should use form PHS-5161. All other applicants should use the standard PHS-398 (Revised 5/82) research grant application form. Mental Illness in Nursing Homes should be typed in item #2 on the face page of the application.

Application kits including instructions may be obtained from most institutional business offices or from offices of sponsored research for most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

Grants Operation Section
National Institute of Mental Health
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

The original and six copies (two copies if PHS-5161 is used) of the application must be sent directly to:

Application Receipt Office
 Division of Research Grants
 National Institutes of Health
 Westwood Building
 5333 Westbard Avenue
 Bethesda, Maryland 20205

III. REVIEW PROCEDURES

Applications will be reviewed for scientific merit and relevance to program goals in accordance with the standard review procedures of the Public Health Service (PHS); that is, each application will be assessed first for scientific merit review by an appropriate Initial Review Group (IRG) of non-Government scientists and then for policy and program relevance by the National Mental Health Advisory Council. Only applications recommended for approval by the Council can be considered for funding.

IV. RECEIPT AND REVIEW SCHEDULE

Applications in response to this announcement will be reviewed according to the following schedule:

<u>Receipt of Applications</u>	<u>Initial Review</u>	<u>Advisory Council Review</u>	<u>Earliest Award Date</u>
Dec. 1, 1984	Feb.-March, 1985	May-June, 1985	July 1, 1985
March 1, 1985	May-June, 1985	Sept.-Oct., 1985	Dec. 1, 1985
July 1, 1985	October, 1986	Feb.-March, 1986	April 1, 1986
Nov. 1, 1985	Feb.-March, 1986	May-June, 1986	July 1, 1986

This initiative will last for two years. Thereafter, applications will be received under the regular receipt schedule and will compete for funding with all other applications.

V. STAFF CONSULTATION

Potential applicants are encouraged to contact Institute state listed below to obtain copies of the complete announcement, including background and criteria for review and award:

Mary S. Harper, Ph.D., R.N. or Barry Lebowitz, Ph.D.
 Coordinator, Long-Term Chief
 Care Programs

Center for Studies of the Mental
 Health of the Aging
 Parklawn Building - Room 11C-03
 5600 Fishers Lane
 Rockville, Maryland 20857

Telephone: (301) 443-1185

Information on the NIA programs is available from:

Zaven S. Khachaturian, Ph.D.
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C-27
Bethesda, Maryland 20205

Telephone: (301) 496-9350

or

Kathleen Bond
National Institute on Aging
National Institutes of Health
Building 31 - Room 4C-32
Bethesda, Maryland 20205

Telephone: (301) 496-3136

ANNOUNCEMENT

COMMUNITY PREVENTION RESEARCH IN ALCOHOL AND DRUG ABUSE

P.T. 34; K.W. 0701042, 0404009, 0404019, 0404003, 0403007, 0403004

NATIONAL INSTITUTE ON DRUG ABUSE

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Application Receipt Dates: First Review Cycle Only - January 2, 1985
Regular Receipt Dates: March 1, July 1, November 1

I. INTRODUCTION

The National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) announce a new research program in community prevention research.

II. BACKGROUND

Despite a general downward trend observed over the last several years, the use/abuse of cigarette, alcohol, marijuana and other drugs continues as a major national and local problem. Research indicates that most approaches to prevention, such as media campaigns, drug education courses or community awareness programs (e.g., health fairs) when implemented separately have limited effectiveness in preventing or delaying the onset of marijuana, tobacco, alcohol and other drug use/abuse. Research suggests, however, that by systematically applying prevention strategies throughout the community in a unified approach which simultaneously involves diverse community elements such as the schools, families, media, and community organizations, it may be possible to reduce the incidence and prevalence of alcohol and drug abuse.

III. RESEARCH GOALS

The goal of this research announcement is to encourage rigorous scientific study of substance abuse prevention technologies at multiple levels in the community (e.g., individual, small group, family, parent groups, community boards) in order to determine their efficacy in preventing the onset of both alcohol and drug use and patterns of abuse. Application characteristics include the following:

This program is described in the Catalog of Federal Domestic Assistance No. 13.279, Drug Abuse Research Program and No. 13.272, Alcohol National Research Service Awards for Research Training. Grants are awarded under the authority of the Public Health Service Act, Section 301 and 515 (42 U.S.C. 241) and administered under PHS grant policies and Federal regulations, 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- o Applications are expected to study multiple intervention strategies targeted at a specific population group.
- o The proposed project must involve at least two of the following: the family, media, schools, natural social support groups, community organizations and relevant health care providers. Further, it is recommended, and priority will be given, to projects which include at least one intervention in each of the areas of behavior change and community development as described below.
- o The research must be designed to allow for the assessment of individual intervention strategies as well as their combined effects at the community level.
- o Inclusion of previously tested program components is encouraged. In addition, the design and testing of innovative program approaches is also encouraged where appropriate to the research hypotheses being tested and the target populations included in the study design.
- o It is expected that proposed research will examine interventions that prevent the use/abuse of both alcohol and drugs.
- o Given the complex nature of substance abuse prevention research, an interdisciplinary research team is recommended.

IV. CONTENT AREAS FOR COMMUNITY INTERVENTION RESEARCH PROJECTS

Research is needed to apply research knowledge of relevant determinants of drug and alcohol use to the design and testing of appropriate multiple component community interventions that promote development of positive health behaviors. Specifically, research is needed to assess multiple strategies for promoting positive psychological and behavioral change, which simultaneously utilize the schools, media, family, friends or social networks to influence these processes. Research is needed to expand knowledge of the efficacy of multiple strategies of social skill development which promote health enhancing behaviors. For example, the combination of media, home and school-based prevention strategies based upon social learning theory might equip youth with generalizable assertiveness skills allowing them to resist peer pressure to use drugs.

In addition, research is needed to design and test prevention strategies that involve community leaders, organizations, and institutions in establishing an environment in which durable positive health behavior change can be developed and maintained. Community involvement and commitment to substance abuse prevention has been traditionally a desired goal of public health programs. However, much has yet to be learned as to the theoretical basis for promoting community involvement and the testing of multiple techniques that will lead to citizen and organizational participation in the prevention of substance abuse.

Research is needed to develop and test a variety of promising models of community/environmental change that capitalize upon existing community leadership and organization in order to activate those social units which can best deliver health education messages, encourage environmental change, and establish community systems to continue substance abuse prevention activities independent of outside grant support.

V. MECHANISMS OF SUPPORT

The support mechanism for this program is the traditional grant in aid. Applicants will plan and conduct their own programs.

VI. REVIEW PROCEDURES AND CRITERIA

Applications received under this announcement will be assigned to the NIDA for review. Applications will be reviewed for scientific merit by a peer review group consisting primarily of non-Federal experts. Since these applications are expected to cut across several fields, special attention will be given to ensuring that appropriate expertise is available for their review.

Applications will receive a secondary review for scientific/technical merit and policy consideration by the National Advisory Councils of the NIDA and the NIAAA. Notification of review outcome will be sent to the applicant upon completion of the review process. Only applications recommended for approval can be considered for funding.

VII. METHODS OF APPLYING

Applications may be submitted by non-profit, for-profit, or public organizations. The regular research grant application for PHS 398 (Rev. 5/82) must be used in applying for these awards. However, State and local agencies should use form PHS 5161 (Rev. 3/79). When applying, type on page one, of item 2 of PHS 398 the name of this announcement--**Community Prevention Research in Alcohol and Drug Abuse.**

Application kits are available from university grant offices: They are also available from the following:

Grants Management Branch
National Institute on Drug Abuse
Parklawn Building - Room 10-25
5700 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-6710

The original and six copies of applications (original and two copies, if PHS 5161 is used) must be submitted to the following address:

Division of Research Grants
Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

VIII. CONSULTATION AND FURTHER INFORMATION

Potential applicants are encouraged to seek preapplication consultation. Preapplication consultation and further information about the program can be obtained from either NIDA or NIAAA by contacting:

National Institute on Drug Abuse

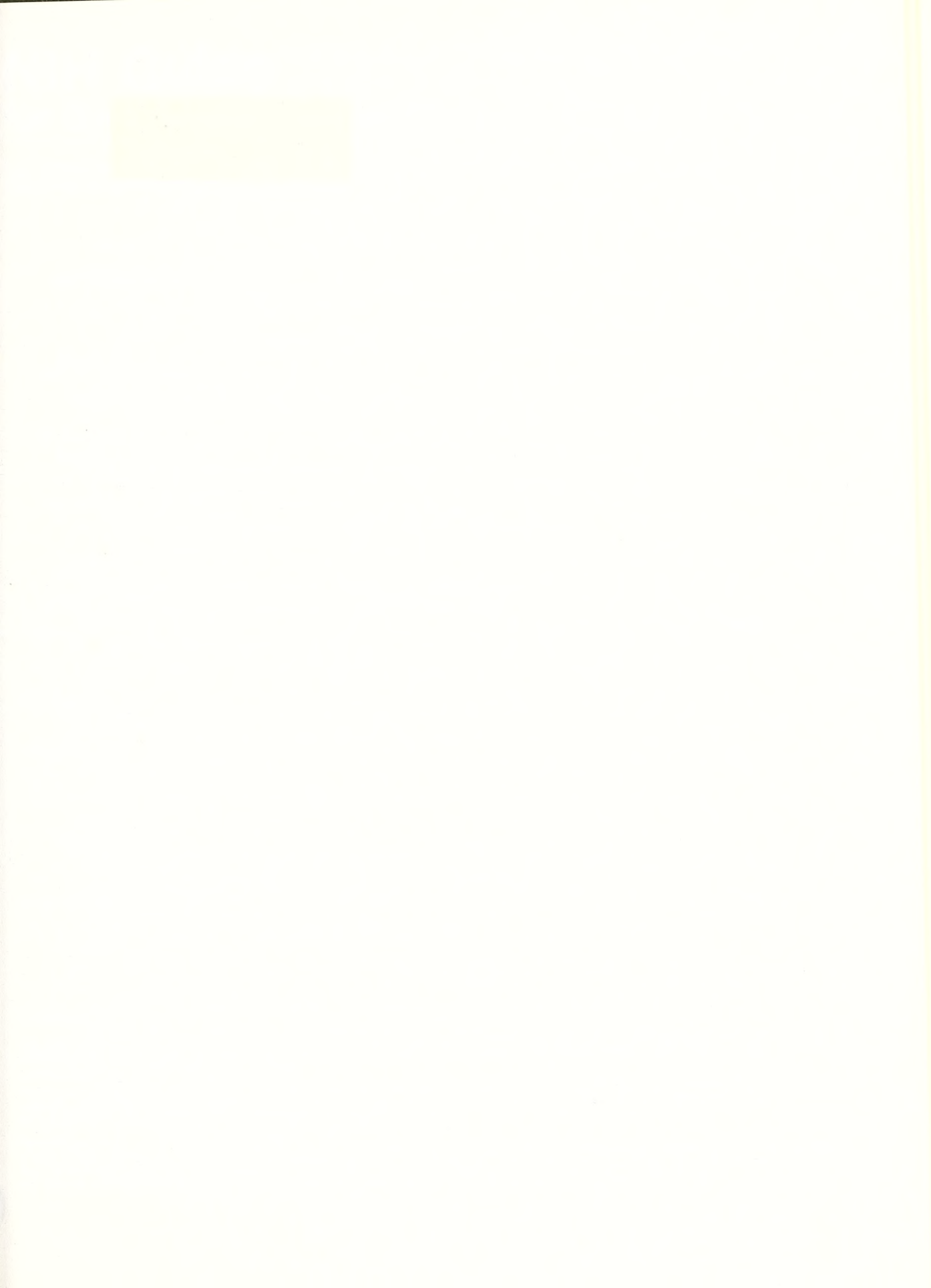
William J. Bukoski, Ph.D.
Research Psychologist
Prevention Research Branch
Division of Clinical Research
Parklawn Building - Room 10A-20
5700 Fishers Lane
Rockville, Maryland 20857

Telephone: 301 - 443-1514

National Institute on Alcohol Abuse and Alcoholism

Ernestine Vanderveen, Ph.D.
Chief, Clinical and Psychosocial Research Branch
Division of Extramural Research
Parklawn Building - Room 14C-17
5700 Fishers Lane
Rockville, Maryland 20857

Telephone: 301 - 443-4223



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NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 13, December 7, 1984

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Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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ERRATUM

THE OLDEST OLD

P.T. 34; K.W. 0404002, 0701013, 0413001, 0408006, 0701016, 0701010, 1201230

THE NATIONAL INSTITUTE ON AGING

Pages 32 and 33 of the November issue of the Guide (Vol. 13, No. 12) were out of order. The full text of NIA's announcement "The Oldest Old" may be found on page 48 of this issue.

NOTICE

SUPPORT OF RESEARCH CENTER AND PROGRAM PROJECT GRANTS

P.T. 34, 04; K.W. 1200180

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Refer to NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 10, No. 4, March 6, 1981

In 1981 the National Institute of General Medical Sciences (NIGMS) published guidelines for support of research center and program project grants which included a budget limit of \$2,750,000 over a 5-year period. Because of increases in the cost of research since then, the NIGMS has decided to raise this limit to \$3,000,000 for all competing applications as of Fiscal Year 1985. All other parts of the 1981 announcement still apply.

For further information call Dr. Elke Jordan, 301 496-7061.

NOTICENATIONAL RESEARCH SERVICE AWARDS FOR SHORT-TERM TRAINING: STUDENTS
IN HEALTH PROFESSIONAL SCHOOLS

P.T. 44; K.W. 1200170

DIVISION OF RESEARCH RESOURCES

The Division of Research Resources (DRR) wishes to announce its withdrawal from participation in the T35, "Short-Term Training: Students in Health Professional Schools", program. This decision is based on a recommendation from the National Advisory Research Resources Council which noted that the T35 program is similar to an activity of the Animal Resources Program (ARP), DRR.

The ARP, DRR supports a summer training program for veterinary students. The students spend up to three months at institutions where ARP-supported diagnostic resources, training grants and Primate Centers are located. Funding is provided by the resource grant and institutional sources, and the students are paid as summer employees. The students are actively involved in ongoing research activities at the centers, usually presenting seminars and frequently co-authoring short papers, as well as gaining clinical experience in laboratory animal medicine. This program will continue and an announcement listing participating institutions and program directors will be sent to all schools of veterinary medicine by January 1, 1985.

NOTICE

CHANGE IN APPLICATION RECEIPT DATE

CANCER CONTROL RESEARCH UNITS: RFA

84-CA-08

P.T. 34; K.W. 1002014, 0701042, 0403004

NATIONAL CANCER INSTITUTE

Revised Application Receipt Date - June 11, 1985
Revised Letters of Intent Receipt Date - February 4, 1985

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites grant applications from interested investigators for the support of Cancer Control Research Units (CCRU).

The receipt dates for applications and letters of intent are revised from those announced for RFA 84-CA-08 in the NIH Guide for Grants and Contracts, Vol. 13, No. 4, March 30, 1984. The new dates are shown above.

Copies of the complete RFA and the 1983 Cancer Control Program Guidelines may be obtained from:

Carlos E. Caban, Ph.D.
Program Director
Cancer Control Applications Branch, DCPC
Blair Building - Room 4A01
National Cancer Institute
National Institutes of Health
9000 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-RR-01DEVELOPING AND IMPROVING INSTITUTIONAL ANIMAL RESOURCES

P.T. 14, 36; K.W. 1002002

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: March 1, 1985

I. BACKGROUND

As part of its mission to create, develop and maintain animal resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is continuing its competitive grant program to help institutions upgrade and develop their animal facilities. The DRR Fiscal Year 1985 appropriation includes up to \$7,369,000 for this purpose.

II. RESEARCH GOALS AND SCOPE

Institutional animal resource improvement projects are awarded to assist biomedical research and educational institutions to upgrade their animal facilities and develop centralized programs of animal care. A major objective is to enable institutions to comply with the Animal Welfare Act and DHHS policies on the care and treatment of animals. Requests of this type may include alterations and renovations to improve laboratory animal facilities and equipment, such as animal cages and cage washers. Other costs directed at improvement of the animal resource may be supported; but it is not the purpose of the improvement grant to provide a general subsidy for the resource; e.g., funding for currently established positions, consumable supplies for routine animal care, etc. The projects are supported for one year, after which the applicant institution is expected to assume complete financial responsibility for its basic animal resource.

This program is described in the Catalog of Federal Domestic Assistance No. 13.306, Laboratory Animal Sciences and Primate Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

To gain approval and support, both the need for resource improvement and a sound plan to bring the entire animal resource up to the required standards must be demonstrated, presented and described in the context of the biomedical research and research training program of the institution. Alteration, renovation and equipment grant requests, per se, will not be acceptable; i.e., requests for such needs will be considered only in relationship to the overall project plan to improve institutional animal resources.

III. ELIGIBILITY AND REVIEW

Nonprofit institutions engaged in health-related research supported by the National Institutes of Health are eligible to apply for animal resource project grants. In general, applicants are expected to develop a single animal resource improvement proposal for campus-wide service.

Applications will be received by the NIH Division of Research Grants (DRG). All applications submitted in response to this RFA will be reviewed in competition with each other by the Animal Resources Review Committee for scientific merit review and the National Advisory Research Resources Council of the DRR for program considerations.

IV. MECHANISM OF SUPPORT

Awards will be made as competitive resource grants for a project period limited to one year. It is expected that from 20 to 30 awards will be made in Fiscal Year 1985. All policies and requirements which govern the grant programs of the PHS apply. The requirement for cost sharing will be fulfilled by the use of matching funds for alterations and renovations.

V. TERMS OF AWARD

Alterations and renovations are limited to a maximum of \$500,000 from this grant program. Equal matching funds are required from nonfederal sources. Support for new construction is not authorized. Funds awarded for alterations and renovations may not be expended until final drawings, specifications, and updated cost estimates are received and approved by the Animal Resources Program, DRR.

VI. INQUIRIES

Inquiries and requests for this RFA should be directed to:

Dr. William I. Gay
or
Dr. John E. Holman
Animal Resources Program
Division of Research Resources
Building 31 - Room 5B59
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5175

ANNOUNCEMENTREQUEST FOR APPLICATIONS: RFA85-OD-01ACADEMIC RESEARCH ENHANCEMENT AWARD

P.T. 34, 14; K.W. 1200180

NATIONAL INSTITUTES OF HEALTH

Application Receipt Date: April 1, 1985

In its report accompanying the Fiscal Year 1985 appropriation for the National Institutes of Health (NIH), Congress called for an initiative to strengthen the research milieu of non-research-intensive, four year, colleges and universities, which provide undergraduate training for a significant number of our nation's research scientists. The NIH will make up to \$5,000,000 available for this purpose through a new type of award entitled the "Academic Research Enhancement Award" (AREA). This award is designed to enhance the research environment of the educational institutions that have not been traditional recipients of the National Institutes of Health (NIH) research funds. The award is intended for the use of faculty members of these institutions to develop new research projects or expand ongoing research activities in areas related to the health sciences.

Institutions eligible for the AREA are defined as those four-year academic institutions that have: 1) provided baccalaureate degrees for 25 or more individuals (irrespective of field of specialization) who have obtained doctoral degrees in the health related sciences since 1977; and 2) received less than \$200,000 (total costs) in Public Health Service (PHS) research grants (exclusive of training grants) in fiscal year 1984. The awards will be made on a competitive basis. Applicants may request support for up to \$50,000 in direct costs (plus applicable indirect costs) over a 24-month period. While this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies and other small-scale projects preparatory to seeking more substantial funding through the traditional NIH grant mechanisms.

Applications for this award will be accepted through the regular application submission procedures of the NIH through its Division of Research Grants (DRG). Grant applications must be prepared and submitted on PHS 398 grant application forms. An abbreviated format and simplified instruction will be provided for use in preparing these applications. The receipt date is April 1, 1985.

Those individuals and institutions qualifying and wishing to receive further information and/or application materials should write to:

AREA
Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-26

ALTERATIONS AND RENOVATIONS TO ESTABLISH NHLBI SHARED RESEARCH

FACILITIES

P.T. 02; K.W. 1200180

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: March 1, 1985

The National Heart, Lung, and Blood Institute (NHLBI) announces a grant program to support the improvement, renovation, and establishment of modern research facilities relevant to contemporary biomedical sciences (e.g., molecular biology) in organizations with substantial, ongoing research activities in heart, lung, and blood diseases. The goal of this program is to expand and/or create physical resources for the application of modern, sophisticated technology to fundamental research in heart, lung, and blood diseases. Any domestic, nonprofit organization with existing, high quality research activities in heart, lung, and blood diseases (that receives at least \$5 million/year total costs, in peer-reviewed NIH support for such research) may apply.

The Institute's appropriation for Fiscal Year 1985 includes \$3.3 million for construction and renovation of research facilities. The use of these funds is limited to the repair, renovation, remodeling, improvement, or creation of facilities utilized by groups of investigators currently being supported by NHLBI. These grants, awarded on a competitive basis, will be limited to a maximum of \$500,000 total costs.

An organization applying for these grants must clearly show that the core research facilities to be established will expand and improve the existing research activities in at least two of the three program areas of the NHLBI--i.e., heart, lung, and blood.

After competitive review, awards (limited to a maximum of \$500,000) will be issued on a matching basis--at least 1/3 to be provided from non-Federal sources.

An institution may submit only one application in response to this Request for Applications. An application may, however, request funds for more than one shared research facility.

TIMETABLE

Letter of Intent	February 1, 1985
Receipt of Applications	On or before March 1, 1985
Initial Review	June-July 1985
Advisory Council Review	September 12-13, 1985
Award Date	September 30, 1985

INQUIRIES

Inquiries concerning this program and requests for copies of the RFA should be addressed to:

Dr. Jerome G. Green
Director
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 7A17B
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-03

REPRODUCTIVE DISORDERS

P.T. 34; K.W. 0413002, 1201070, 1201010

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: April 1, 1985

The Reproductive Sciences Branch (RSB) of the Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD), invites research grant applications for clinical studies in reproductive disorders in women. An important component of increasing human age-specific infertility rates appears to be comprised of some relatively common functional and structural disturbances of the female reproductive tract leading to impaired fertility and sterility. In some cases evidence of the increased incidence of these disturbances of function has been well documented. Seeking to encourage investigator interest in these specific research areas appropriate to the mission of the Institute, the RSB hopes to receive grant-in-aid requests (R01) for studies conducted in the human pertinent to disturbances in hypothalamic-ovarian function, pelvic endometriosis, and ectopic pregnancy. It is anticipated that such studies will deal with pathophysiology and disturbances of biological mechanisms, the delineation of the natural course of disease, and the application of new modes of investigation to these topics. The Reproductive Sciences Branch anticipates that 10-12 applications will be funded as a result of this RFA.

For further information and a copy of the RFA, contact the following:

Thomas H. Kirschbaum, M.D.
or
Julia Lobotsky, M.S.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7C33
Bethesda, Maryland 20205

Telephone: 301/496-6515

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

FDA-OP-85-1

CLINICAL STUDIES OF SAFETY AND EFFECTIVENESS OF ORPHAN PRODUCTS

P.T. 34; K.W. 1200270, 0701038

FOOD AND DRUG ADMINISTRATION

Application Receipt Date: February 5, 1985

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of funds for Fiscal Year 1985 for awarding grants to support clinical trials on safety and effectiveness of orphan products. FDA has funds to award approximately 20 to 30 grants ranging from \$20,000 to \$70,000. The agency will consider grants greater than \$70,000 if they extend over a 2- or 3-year period.

I. BACKGROUND

FDA has established an Office for Orphan Products Development to identify and facilitate the availability of orphan products. Orphan products are drugs, biologics, medical devices (including in vitro diagnostics), foods for medical purposes, and veterinary products that may be useful in an uncommon or common disease but lack committed commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products for which there is evidence suggesting usefulness in an uncommon, serious disease but which are not labeled for that disease because substantial evidence is lacking.

One way to make orphan products more easily available is to support research to determine whether the products are safe and effective. FDA has allocated funds to support such research.

II. RESEARCH GOALS AND OBJECTIVES

Clinical Studies: FDA will consider only clinical studies for determining whether the products are safe and effective for premarket approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including the addition of new uses to marketed drugs. Ordinarily, there should already be available at least some preliminary clinical research suggesting effectiveness and relative safety. FDA will also consider applications where persuasive pharmacologic evidence is available that a product has a reasonable possibility of being effective even though no clinical trials have yet been performed. All studies subject to requirements for clinical investigations under the Federal Food, Drug, and Cosmetic Act are to be conducted in accordance with those requirements in addition to the requirements of the request for application (RFA).

Because funds are relatively limited, FDA cannot consider large research projects involving many subjects (human, or animal in the case of a veterinary drug) and long-term followup. The typical study considered for support may involve up to several dozen subjects, will be well-controlled and directed to providing substantial evidence of the product's safety and effectiveness. Pharmacokinetic studies will also be considered if they are necessary to determine safe and effective doses in subjects with serious organ disease that might affect drug disposition. But pharmacokinetic studies will be considered only if they are part of studies for determining effectiveness of a drug or are proposed as desirable information to obtain for drugs that are already shown to be effective. In designing a well-controlled study, the investigator should keep in mind that historical controls or use of the subject as his or her own control are generally less desirable and reliable than active control or, when ethical, placebo controls.

Each investigator submitting a grant application (human or veterinary use) in response to this RFA must include a 1/2 to 1 page rationale as to why his or her product is appropriate to the objectives of the orphan products grants program as outlined in this notice. In the case of veterinary products, research studies should be directed to the following area only: a true orphan animal product for which the animal disease being studied can be transmitted to man.

In addition to FDA's general interest in clinical studies for the safety and effectiveness of orphan products, the agency is also interested in receipt of applications on gamma-hydroxybutyrate for the treatment of narcolepsy. These applications will compete with others received in response to this RFA. Only one application for this purpose will be awarded, however.

III. STAFF CONTACT

Copies of the complete RFA and additional information may be obtained from:

Benjamin P. Lewis
Health Scientist Administrator
Office of Orphan Products Development (HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS:MH-86-02AMERICAN INDIAN MENTAL HEALTH RESEARCH AND DEVELOPMENT CENTER

P.T. 34, 04; K.W. 1200180, 0701029, 0403004, 1200170

NATIONAL INSTITUTE OF MENTAL HEALTH

Application Receipt Date: March 1, 1985

I. PURPOSE

The National Institute of Mental Health (NIMH) will award a grant to support an American Indian Mental Health Research and Development Center which will develop and carry out innovative, multidisciplinary studies on the mental health problems and needs of American Indians. The Center should have a nucleus of experienced mental health researchers who will direct their energies toward the conceptualization, development, and conduct of research programs addressing the incidence, diagnosis, treatment, and prevention of mental illness among American Indian populations. Research activities that primarily focus on gaining insight into the nature of mental illness and its expression in American Indian populations through the development of methodologically sound studies should be a major objective of the Center. In addition, the Center should serve as a resource for the training of both new and established American Indian mental health researchers; disseminate information stemming from the Center's ongoing research programs via appropriate scientific and professional outlets; and provide an environment which will assure high-level research leadership in the area of American Indian mental health.

II. CENTER CHARACTERISTICS

The Center should develop a program in accordance with its resources, talents, opportunities, objectives, and constraints. While there is no one prescribed focus for the Center, it should have a rich research environment wherein hypothesis development and testing can unfold in the context of both pilot and more comprehensive studies, and where new methodologies and data-gathering techniques can be formulated, tested, and developed.

The Center must be problem oriented, comprehensive, and integrative, as well as multidisciplinary when possible. It is expected that:

- o The Center will provide an environment of research excellence which will ensure the promotion and conduct of scientifically sound investigation in the area of Indian mental health. In these activities, the Center should be regarded as a national resource by the surrounding scientific and American Indian communities in research areas of importance to the American Indian populations.

- o The Center will focus on a clearly defined set of research objectives or set of scientific problems of major importance to the understanding of American Indian mental health needs. The attempt to provide insights into the resolution of these problems should stem from the development and implementation of theoretically and methodologically sound investigations. The Center's research focus must fall within the research areas described in the July 1984 revised announcement of "NIMH Research Support Programs."
- o The Principal Investigator will be the Director of the Center, providing leadership for the scientific program and having responsibility for the scientific, administrative, and operational aspects of the Center's programs. He or she is responsible for the overall development of the Center as a resource to the scientific community and, as such, is expected to devote full time to the project. The Director must be a highly knowledgeable, experienced research investigator with appropriate administrative skills who will ensure the highest standards of scientific investigation.
- o The Center is expected to have an administrative structure that will ensure maximum effectiveness and efficiency of operation and sound financial practices. The administration will be responsible for program planning, monitoring, and execution and preparation of the budget and control of expenditures, staff appointments, and space allocation.
- o While the primary purpose of the Center is the development and implementation of research investigations, the training of both pre- and post-doctoral researchers in the area of American Indian mental health research issues, and the special methodological problems encountered in the systematic investigation of these populations, should be an important activity of the Center. Accordingly, the Center should specify its relationships with other institutional professional and academic training programs, particularly as these apply to graduate and post-graduate levels of training. While the Center should be appropriately involved in training researchers, funds from the Center grant may not be used to support training activities. Funds to support research training may be sought under the National Research Service Award Program.
- o In addition, the Center may provide supervised research experiences for up to two preceptees annually (precepteeships are defined as supervised work experience). Funds for these precepteeships may be included in the requested budget.
- o It is expected that the Center will build a technical assistance capability steadily over the period of the grant. Such technical assistance should involve consultation to agencies and groups which conduct research programs on the mental health needs of American Indians, and include participation and leadership in workshops, conferences, and meetings designed to share research knowledge on American Indian mental health issues with other researchers and interested agencies and groups.
- o The Center is expected to disseminate information from its research activities through publication in appropriate scientific and professional outlets; the development of a bibliographic resource; the publication of monographs, occasional papers, and research bulletins; and the presentation of papers at scientific meetings.

- o The Center is expected to demonstrate a capability to recruit experienced researchers, especially American Indians.

III. ELIGIBLE APPLICANTS

The American Indian Mental Health Research and Development Center applicant must be an organization which demonstrates experience and capability in conducting mental health research. Furthermore, it must have a strong relationship or base in a research-oriented facility, agency, or institution. In-depth experience with American Indian mental health issues and access to American Indian populations are vital. Eligible applicants include any U.S. nonprofit or for-profit organizations capable of meeting the stated criteria.

IV. STAFF CONTACT

For guidelines specific to Center applications and for General Instructions for Application for Research Grant, applicants should contact:

Dr. James R. Ralph
Chief, Center for Studies of Minority Group
Mental Health
Division of Prevention and Special Mental
Health Programs
National Institute of Mental Health
Parklawn Building - Room 11-95
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-3724

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-07

SMOKING PREVENTION AND CESSATION AMONG WOMEN

P.T. 34; K.W. 0404019, 0701013

NATIONAL CANCER INSTITUTE

Application Receipt Date: March 15, 1985
Letter of Intent Receipt Date: February 15, 1985

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI), is interested in supporting studies to determine the long-term effect of interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking among women.

The proposed studies should seek to: (1) develop and evaluate innovative intervention strategies to prevent or reduce cigarette smoking among women and (2) develop and evaluate assessment procedures for determining the long-term effectiveness of smoking interventions among women.

The purpose of this RFA is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on U.S. female populations and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among women.

The focus of the studies envisioned thus must be on the long-term effectiveness of interventions aimed at women. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of results of the larger population) and Phase IV (i.e., interventions designed and carried out with a sample of the population in such a way that the results obtained are representative of results in large target populations) investigations.

It is recognized, however, that there are substantial gaps in our knowledge concerning smoking among women, and, in particular, knowledge that may be tion program. Therefore, where necessary and specifically justified in the application, highly controlled studies of the acquisition process, epidemiological issues or other related research questions which could influence the effectiveness of prevention/cessation efforts may be addressed in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external economic or technical aid.

I. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

II. MECHANISM OF SUPPORT

Awards will be made as grants. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years.

III. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year.

IV. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Gayle M. Boyd (see address in Section V.) by February 15, 1985.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by March 15, 1985, to ensure their review.

V. REQUESTS FOR COPIES OF RFA AND INFORMATION

To obtain a copy and/or other information, please contact:

Gayle M. Boyd, PH.D.
Smoking, Tobacco, and Cancer Program
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Balir Building - Room 425A
9000 Rockville Pike
Bethesda, Maryland 20205 - 4200

Telephone: (301) 427-8620

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-08

PREVENTION AND CESSATION OF USE OF SMOKELESS TOBACCO

P.T. 34; K.W. 0701042, 0404001

NATIONAL CANCER INSTITUTE

Application Receipt Date: March 15, 1985
Letter of Intent Receipt Date: February 15, 1985

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI) is interested in supporting studies designed to develop and evaluate the effectiveness of interventions to prevent the onset and reduce the prevalence of smokeless tobacco use in the United States.

The proposed studies should seek to: (a) identify patterns of smokeless tobacco use and the primary factors influencing such use; (b) develop and evaluate intervention strategies to reduce the incidence and prevalence of smokeless tobacco use; and (c) develop and evaluate assessment procedures to determine the long-term effectiveness of these intervention strategies.

I. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on the use of smokeless tobacco and determining the long-term effectiveness of these programs on the prevention and cessation of smokeless tobacco use. The focus of the studies envisioned must be on the long-term effectiveness of interventions.

It is anticipated, in keeping with the goals of the NCI Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out within a large and defined population in such a way that the results obtained are representative of results in large target populations) investigations.

It is anticipated that proposals will use a phased-in approach in which, during the first year, data describing the target population, prevalence, and patterns of use are obtained, unless such data are already available, and proposed interventions are pilot tested. Only at this point would interventions be initiated on a full scale. Information collected during the first year could be used to modify and adapt the proposed interventions as needed. In subsequent years interventions should be expanded with a major focus on evaluation of the interventions' effectiveness.

The objective of these studies is to develop intervention strategies and to evaluate their effectiveness in preventing or reducing the prevalence of smokeless tobacco use. No restrictions are placed on the type of interventions. Any population subgroup may be chosen for study provided there is reasonable evidence that it contains a sizeable number of smokeless tobacco users or individuals who are at risk for initiating use (e.g., targeted by tobacco advertising; observed trends toward increased use; use by an immediately older cohort).

Prospective investigators should note (1) that the outcome measure of these studies should be smokeless tobacco use, not cancer incidence/mortality, and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; and d) readily adoptable by others with only those modifications that are necessary for a broad community/population impact.

II. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

III. MECHANISM OF SUPPORT

Awards will be made as grants. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant.

The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year.

V. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Gayle M. Boyd (see address in Section VI) by February 15, 1985.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by March 15, 1985, to ensure their review.

VI. REQUESTS FOR COPIES OF RFA AND INFORMATION

To obtain a copy and/or other information, please contact:

Gayle M. Boyd, Ph.D.
Smoking, Tobacco, and Cancer Program
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 425A
9000 Rockville Pike
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8620

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH - GENERAL PROGRAM ANNOUNCEMENT

P.T. 34, 04; K.W. 0701018, 1200180

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Initial Application Receipt Date: March 1, 1985
Subsequent Receipt Dates: June 1, October 1, February 1

I. INTRODUCTION

The National Institute of Environmental Health Sciences (NIEHS) serves as a national resource and focal point for support of environmental health research and research training. Its mission is to develop understanding of pathological processes as they relate to the etiology, diagnosis, treatment and prevention of diseases and disorders caused by environmental factors, and to facilitate research training of environmental health scientists in accordance with identified national needs. A number of support mechanisms are used by the extramural program to provide funding for research in environmental health sciences. The regular research project grant (R01) is the major mechanism for support of individual projects. Other mechanisms such as core center grants and program project grants are utilized where multiple, interdisciplinary, and closely related projects are proposed or where core support is deemed appropriate to support centers of excellence in environmental health research. These guidelines introduce the NIEHS Specialized Center of Research (SCOR) for support of core facilities and related research projects. Specific scientific areas to be supported by this mechanism will be announced separately.¹

II. DEFINITION OF A SCOR

A. Mechanisms for Funding

The funding mechanism most commonly used by the Institute to support a group of closely related, but discrete projects is the Program Project Grant (P01). Such grants support a minimum of three related research projects which focus on a single research topic within the Institute's purview. Although not a center grant, a program project grant may receive funds for the laboratory facilities, research services, and administrative assistance shared by the projects in the grant. Funding for support services used jointly is called "core support."

For a research field deemed to be of special importance and one requiring a funding mechanism beyond the scope of a program project grant, the Institute

¹ For areas of research currently eligible for SCOR funding, see the following three announcements.

makes funds available under the center grant mechanism. Two types of center grants are available: a Center Core Grant (P30) or a Specialized Center of Research Grant (P50).

A Center Core Grant (P30) is the appropriate funding mechanism when a large number of funded research projects of high quality relevant to the mission of the NIEHS exists in an institution and core support only is needed. This core support serves to enhance quality and productivity, promote collaboration, encourage additional research in the field, and improve cost-effectiveness.

A Specialized Center of Research Grant (P50) provides support for both the research projects and the core support services in one grant. An application for a P50 grant is developed in response to a request by the NIEHS when the Institute seeks to stimulate research in a given field by encouraging collaborative interdisciplinary research on one or more problems.

B. Scope

A NIEHS SCOR grant is an institutional award, made in the name of a principal investigator, for the support of a large interrelated research program developed in response to a request by the NIEHS for research focused on a specific problem. It is awarded competitively, initially for not less than 3 or more than 5 years, and may be renewed for periods up to 5 years. It provides support for both research projects and the core support services used by those projects. The activities included in the supported research comprise a multidisciplinary approach to environmental biomedical and/or behavioral problems.

Beyond meeting the standard eligibility criteria for institutions applying for NIH research grants, an applicant for a P50 Specialized Center of Research (SCOR) Grant must propose a program of three or more related and integrated research projects of high quality that provided a multidisciplinary, yet unified, approach to the problem(s) to be investigated. Scientific personnel and institutional resources capable of providing a strong research base in the field specified must be available. The institution and pertinent departments have to show a strong commitment to the center's support.

C. Characteristics

A NIEHS Specialized Center of Research (SCOR) is an identifiable unit within a sponsoring institution with a strong commitment to a specific activity in the field of environmental health. Each SCOR conducts its own research program based on local interest and talents. Each research program consists of a sustained series of individual, but closely related, research projects, each with high scientific merit and clear research objectives. A SCOR may address more than one issue; however, a central theme unifying the research projects is required. A SCOR may also include one or more core resources, which perform specialized service activities such as biochemical analysis, pathology, or data management. These activities are shared by several or all investigators. The core investigators, in addition to performing service functions, may also conduct research projects.

Investigators participating in a SCOR must be of recognized ability, capable of conducting independent research, and willing to make long term commitments to the goals of the SCOR. SCOR scientists should have access to facilities where innovative fundamental and/or clinical investigations can be conducted.

D. SCOR Director

The SCOR Director must provide strong, effective administrative and scientific leadership. The Director is responsible for the organization and operation of the center and for communication with the NIEHS on all scientific and operational matters. The SCOR Director is responsible for maintaining high quality research throughout the funding period. New projects within the budgetary and scientific scope of the grant may be incorporated into the program at any time at the discretion of the Director with final review and approval by the NIEHS. SCOR grantees are thus encouraged to pursue promising research leads. By the same token, if a Director deems it advisable to discontinue a project, NIEHS staff should be consulted before implementing the decision. Each SCOR Director must encourage and support close collaboration between individual SCOR investigators by means of frequent seminars and scientific meetings.

Each SCOR Director must establish both internal and external advisory committees which will periodically assess the overall program as well as the progress of individual projects. The external advisory committee must consist of expert consultants from outside the grantee institution and must meet annually. The NIEHS program officer may attend these meetings as an observer.

E. Relation to the NIEHS

A SCOR is a grant-in-aid which differs from other research grants in its focused goal orientation. The award of a SCOR grant will establish a special relation between the NIEHS and the grantee institution. The NIEHS program officer will monitor the program and, when requested, provide advice to the Director and staff of each SCOR. SCORs may be asked to perform additional studies on research problems within the scientific scope of the SCOR in order to respond to unexpected opportunities or problems of special public concern. They may serve as a regional or national resource for special purpose research. Funding for such activities would be provided through supplements to the award provided by established NIH/NIEHS procedures.

III. Mechanism of Support

The support mechanism will be the research grant-in-aid for a period of up to five years. However, it will differ from other research grants in the expected communication among Centers and periodic structured review of progress by the NIEHS.

Applicants are expected to furnish their own estimates of the time required to achieve specific objectives of the proposed work, a schedule for completion of the work, and an outline of the phases or segments into which the proposed program

can be logically divided. The NIEHS-SCOR will plan, direct and execute its own research program. As with any research grant, substantial modifications must be mutually agreed upon by the NIEHS-SCOR institution and the NIEHS.

Additionally, a two-day meeting of all SCOR Program Directors and one or two senior investigators, and NIEHS program staff, will be held at least annually. Applicants should include a request for travel funds for these meetings in each year of the budget. Applicants should also include a statement in the application indicating willingness to participate in such meetings.

IV. Review Procedures and Criteria

The applications will be evaluated in national competition with each other. Primary review will be conducted by a review group of predominantly non-federal consultants with selected scientific expertise and may include a site visit. Secondary review will be by the National Advisory Environmental Health Sciences Council.

Applications considered non-responsive will be returned to the investigator. Major factors to be considered in the evaluation of responsive applications will include:

1. The scientific merit of each proposed project, including the novelty, originality and feasibility of the approach and the adequacy of the experimental design.
2. The technical merit and justification of each core unit.
3. The competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the program.
4. The adequacy of facilities to perform the proposed research including the laboratory and clinical facilities, if applicable, and the proposed instrumentation and data management systems, when needed.
5. The integration of the various projects and core units into an effective center, and the adequacy of plans for interaction and dissemination of information among investigators.
6. The qualifications, experience and commitment of the SCOR Director and the ability to devote adequate time and effort to provide effective leadership to the Center.
7. The scientific and administrative structure of the program, including adequate internal and external procedures for monitoring the proposed research and for providing ongoing quality control and scientific review.
8. The institutional commitment to the program, and the appropriateness of its resources and policies for the administration of a research program of the type proposed.
9. The willingness to work cooperatively with other NIEHS Centers, Specialized Centers of Research, and with the NIEHS.

10. The appropriateness of the budget for the proposed program.

V. Method of Application

A. Letter of Intent

Prospective applicants are asked to submit a letter of intent which includes a synopsis of proposed areas of research and identification of any other participating institutions. This letter should be received no later than six weeks prior to the NIH Division of Research Grant receipt dates for these proposals (February 1, June 1, October 1)¹ and should be addressed to:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

The Institute requests such letters only to provide an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not enter into the review of any proposal subsequently submitted, nor is it a necessary requirement for application.

B. Format for Application

Applications should be prepared on PHS Form 398, available at most institutional business offices or from the Division of Research Grants, NIH. Supplemental instructions for using the form PHS 398 for SCOR applications are available from the Program Director indicated above and should be obtained by prospective applicants

C. Application Procedure

The signed original and four copies of the application should be mailed to the Division of Research Grants (DRG) (see PHS 398 instructions, p. 8). Two copies should be sent to the Program Director indicated above.

This program is described in the Catalog of Federal Domestic Assistance No. 13.894, Resource and Manpower Development. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

¹ For the first cycle of applications, the receipt date will be March 1, 1985.

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH (SCORs) IN CENTRAL NERVOUS SYSTEM

NEUROTOXICOLOGY

P.T. 34, 04; K.W. 1007009, 1200460, 1007001, 1002028, 1201270, 1002014

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for the support of research dealing with the effects of environmental agents on human health. The Institute supports efforts to develop new knowledge to better understand the means by which exposures to environmental agents cause deleterious health effects in humans. Though not participating directly in this announcement for research centers, the National Institute of Neurological and Communicative Disorders and Stroke (NIADDK) also has major responsibilities for a research grant program in neurotoxicology.

I. BACKGROUND

The National Institute of Environmental Health Sciences (NIEHS) pursues its mission by supporting basic and applied research on the consequences of the exposure of man to potentially toxic or harmful agents in the environment. Research of interest encompasses studies which relate to the biological effects of environmental chemicals and other factors to which humans might be exposed through air, food, or water in the general, home, recreational, or work-place environments.

Therefore, the NIEHS supports research to attempt to learn the causal associations between human disease and hazardous chemical, physical, and biological environmental factors and the processes by which these environmental agents affect biological systems and result in human diseases and disorders. In addition, the Institute is interested in supporting research projects to develop reliable test systems for determining which environmental agents are potentially hazardous to humans due to their mutagenic, teratogenic, carcinogenic, or otherwise toxic actions. Underlying the NIEHS support programs is the desire for a better understanding of the molecular and cellular mechanisms of the toxic actions of these agents.

II. RESEARCH GOALS AND SCOPE

The NIEHS wishes, through the establishment of Specialized Centers of Research (SCOR(s)), to focus research on the fundamental mechanisms involved in neurotoxic actions of environmental chemicals on human brain cells. A direct approach on this problem has become feasible since it is now possible to fractionate complex brain tissues into homogeneous parts and to maintain these individual nerve cells in vitro. This should allow biochemical approaches to be used to study the effects of environmental toxins on these tissues and to relate these to previous and current studies of neuropathological and behavioral changes.

A NIEHS SCOR in Neurotoxicology, therefore, should have as its theme the mechanisms of action of xenobiotics on specifically located neurons in the mammalian brain. This may include studies of metabolism and activation of the parent compound, functional changes due to the xenobiotic, etc.

It is expected that proposed studies will be of a collaborative nature involving a number of different scientists and scientific projects supported by common core facilities. Reference is made to the general program announcement for NIEHS SCORs published elsewhere in this issue of the NIH Guide for Grants and Contracts.

Individuals wishing additional information or having questions concerning this program announcement should contact:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

Telephone: (919) 541-7634

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH IN MARINE AND FRESHWATER BIOMEDICAL
SCIENCES (MFBS SCORs)

P.T. 34, 04; K.W. 1007001, 1007002, 1007003, 1200460

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for the support of research dealing with the effects of environmental agents on human health. The Institute supports efforts to develop new knowledge to better understand the means by which exposures to environmental agents cause deleterious health effects in humans.

I. BACKGROUND

The National Institute of Environmental Health Sciences (NIEHS) pursues its mission by supporting basic and applied research on the consequences of the exposure of man to potentially toxic or harmful agents in the environment. Research of interest encompasses studies which relate to the biological effects of environmental chemicals and other factors to which humans might be exposed through air, food, or water in the general, home, recreational, or work-place environments.

Therefore, the NIEHS supports research to attempt to learn the causal associations between human disease and hazardous chemical, physical, and biological environmental factors and the processes by which these environmental agents affect biological systems and result in human diseases and disorders. In addition, the Institute is interested in supporting research projects to develop reliable test systems for determining which environmental agents are potentially hazardous to humans due to their mutagenic, teratogenic, carcinogenic, or otherwise toxic actions. Underlying the NIEHS support programs is the desire for a better understanding of the molecular and cellular mechanisms of the toxic actions of these agents.

II. RESEARCH GOALS AND SCOPE

The NIEHS is interested in receiving applications for Marine and Freshwater Biomedical Sciences Specialized Centers of Research (MFBS SCORs) to support marine and freshwater biomedical programs which would be of significant value to the NIEHS in carrying out its mission of generating new knowledge on the direct effects of environmental chemicals and other factors on human health. The goal of this program, therefore, is to encourage groups of researchers involved in marine and freshwater biomedical research to focus their efforts on the utilization of aquatic species as models for these disease processes.

It is expected that proposed studies will be of a collaborative nature supported by common core facilities. Reference is made to the general program announcement for NIEHS SCORs published elsewhere in this issue of the NIH Guide for Grants and Contracts.

Individuals wishing additional information or having questions concerning this program announcement should contact:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

Telephone: (919) 541-7634

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH IN GENETIC TOXICOLOGY

P.T. 34, 04; K.W. 1002019, 100703, 1002008, 1002028, 1200460

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for the support of research dealing with the effects of environmental agents on human health. The Institute supports efforts to develop new knowledge to better understand the means by which exposures to environmental agents cause deleterious health effects in humans.

I. BACKGROUND

The National Institute of Environmental Health Sciences (NIEHS) pursues its mission by supporting basic and applied research on the consequences of the exposure of man to potentially toxic or harmful agents in the environment. Research of interest encompasses studies which relate to the biological effects of environmental chemicals and other factors to which humans might be exposed through air, food, or water in the general, home, recreational, or work-place environments.

Therefore, the NIEHS supports research to attempt to learn the causal associations between human disease and hazardous chemical, physical, and biological environmental factors and the processes by which these environmental agents affect biological systems and result in human diseases and disorders. In addition, the Institute is interested in supporting research projects to develop reliable test systems for determining which environmental agents are potentially hazardous to humans due to their mutagenic, teratogenic, carcinogenic, or otherwise toxic actions. Underlying the NIEHS support programs is the desire for a better understanding of the molecular and cellular mechanisms of the toxic actions of these agents.

II. RESEARCH GOALS AND SCOPE

The NIEHS, as part of its mission, attempts to elucidate the possible causes of environmentally-induced mutations. It has now become possible to identify and measure DNA reaction products and the particular kinds of genetic changes in animal tissues and in bacterial and mammalian cells. The identification and quantitation of these DNA adducts indicates metabolic pathways and the identity of the most probable premutagenic lesions for each compound studied. Thus, insight into the potential mutagenicity of environmental agents can be obtained.

Through the establishment of a NIEHS SCOR (or SCORs) in Genetic Toxicology, the Institute wishes to focus efforts on this goal. Proposals, therefore, should have as their theme the investigation of the molecular mechanisms of the genetic effects of environmental agents. Examples of activities within this theme include the development of methods to reliably quantify DNA reaction products in human tissues, chromosomal structure changes and replication sequelae subsequent to interaction with environmental chemicals, the relationship between these DNA

reaction products and the metabolism of the chemical, the use of DNA reaction product analysis to determine cases of exposures to agents, the degree of competence of repair mechanisms, etc.

It is expected that proposed studies will be of a collaborative nature involving a number of different scientists and scientific projects supported by common core facilities. Reference is made to the general program announcement for NIEHS SCORs published elsewhere in this issue of the NIH Guide for Grants and Contracts.

Individuals wishing additional information or having questions concerning this program announcement should contact:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

Telephone: (919) 541-7634

ANNOUNCEMENT

NIADDK, DDEMD SCIENTIFIC INSTRUMENTATION GRANTS

P.T. 18; K.W. 1002024, 1004019, 1014001

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, DIGESTIVE AND KIDNEY DISEASES

Application Receipt Date: April 15

The Division of Diabetes, Endocrinology and Metabolic Diseases (DDEMD), NIADDK, announces the availability of funds for the purchase of moderately priced scientific instrumentation (\$5,000 to \$50,000).

I. PROGRAM SPECIFICATIONS

A. Program Objectives

This program is being established to provide a mechanism for biomedical researchers to update and expand their capabilities to perform state-of-the-art research. This program is designed to fill the gap between large, expensive instrumentation grants provided by the Biomedical Research Support Grant Program (BRS) of the Division of Research Resources (DRR) (greater than \$100,000) and individual project grants (R01).

B. Research Scope

Applications under this program will be limited from \$5,000 to \$50,000 (direct costs) for a single instrument system (may be multi-component). Potential instruments might include high pressure liquid chromatography, centrifuge/ultracentrifuge/rotors, scintillation/gamma counter, personal computer, amino acid analyzer/sequencer, spectrophotometer, incubator, tissue culture hood, microscope/electron microscope (partial) or mass spectrometer/gas chromatograph (partial). The preceding list should not be construed to be all inclusive. Funds will not be provided for space renovation, installation, maintenance contracts, technical personnel or operation of commercial instruments.

C. Mechanism of Support

The mechanism of support will be the grant-in-aid. Grants will be awarded as supplements to the Principal Investigator's active R01 grant.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.847, Diabetes, Endocrinology, and Metabolic Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301, (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. METHOD AND CRITERIA OF REVIEW

A. Eligibility

The Principal Investigator (P.I.) must hold an active R01 grant supported by DDEMD related to the proposed use of the instrument. Co-investigators must have active research grant support (R01) from the NIH. Each P.I. and co-investigator can only have his/her name listed on one application under this Program Announcement per year.

B. Criteria for Review

The specific type and model of instrument chosen should be justified by identification and comparison with other available instruments. Comparable instruments at the submitting institution or to which the applicant might have access, should be inventoried and the reason they are unavailable or unsuitable for the proposed research explained. It is important to describe how maintenance and operation costs will be met (where applicable), how time on the instrument will be allocated and the qualifications of the person(s) immediately in charge of the instrument. Shared costs with other sources (i.e., institutional, private, other NIH support) are strongly recommended. Assumption of part of the capital costs by the submitting institution is highly desirable as an indication of its commitment to the proposed research.

The inclusion of multiple investigators and/or projects to share the proposed equipment is strongly recommended. The scientific merit of the underlying R01's will not be an issue during review of this proposal but each investigator must describe their research projects in sufficient detail to permit evaluation of relevance and capability of the requested instrument to experimental goals. Each investigator should limit this description to no more than four pages. A short biographical sketch, list of recent publications and a listing of current and pending research support from all sources for each investigator should be included (as in form PHS 398).

C. Mechanism of Review

Applications in response to this solicitation will be reviewed in competition with each other by an initial review group of scientific consultants established in accord with the usual National Institutes of Health (NIH) peer review procedures. The Advisory Council of the NIADDK will then provide secondary review. This process will be expedited so that awards may be made approximately six months from the application deadline.

III. METHOD OF APPLICATION

A single yearly reply date of April 15 will be strictly established.

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. On the face page of form PHS 398 use the title of the P.I.'s active R01 grant followed by "Supplement" as the project title (line 1), and indicate that the application was prepared in response to the Program Announcement entitled "NIADDK, DDEMD Scientific Instrumentation Grants" (line 2).

The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries can be addressed to

Dr. Robert E. Silverman
DPB/DDEMD/NIADDK
Westwood Building - Room 605
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7888

ANNOUNCEMENT

NIAID MINORITY RESEARCH ENHANCEMENT PROGRAM

P.T. 34, 144;; K.W. 1200180, 0403013

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

I. DESCRIPTION

The National Institute of Allergy and Infectious Diseases (NIAID) will provide support for under-represented minority researchers through the Minority Research Enhancement Program (MREP). A minority investigator is defined as a Black, Hispanic, Native American, Asian or Pacific Islander.

Institutions with NIAID grants and interested in including under-represented minority investigators in such research endeavors may submit a supplemental grant application for this purpose. Meritorious applications will be funded as supplements to previously peer-reviewed active grants. These may include, but are not limited to, regular research project (R01) and program project (P01) grants.

II. OBJECTIVES

The MREP will provide this support to NIAID-supported principal investigators for the purpose of (1) increasing the number of under-represented minorities actively pursuing research objectives relevant to the mission of the institute, and (2) strengthening funded projects by enlarging the pool of scientific talent.

III. PROJECT EVALUATION

A group composed of NIAID staff will evaluate applications for responsiveness of the requested supplemental support to this announcement using as criteria the degree to which:

- o Activities proposed under the supplemental request would fit within the scope of the funded project.

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research and No. 13.856 Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- o The background of the minority scientist indicates that the research objectives will be achieved.
- o A fit exists between the time requested and the comprehensiveness and complexity of the project as proposed for revision/expansion.

The initial review for scientific merit will be conducted and managed by the Extramural Activities Program, NIAID. Recommendations will be forwarded through the director of the program responsible for the prime award to the National Advisory Allergy and Infectious Diseases Council.

IV. ELIGIBILITY

Any institution with an active NIAID research grant is eligible to submit a supplemental application on behalf of a principal investigator for the purpose of including under-represented minority researcher(s) in the project.

- A. Under-represented Minority Investigator - The minority investigator may be affiliated with the applicant institution(s) or some other institution. This investigator is expected to provide a complete curriculum vitae which includes a list of any research publications and other evidence of meritorious scientific achievements. The program is not intended to pay stipends for student trainees or support candidates without any research background. The minority investigator must be willing to devote a minimum of 30 percent of his/her time to the research project.
- B. Research Project - The proposed research project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort in an already approved objective of the research project or propose a new objective related to those already approved. The nature of the research should provide the minority investigator an opportunity to contribute intellectually to the program and to broaden his/her own potential. The scope of the proposed research project should generally be comprehensive enough to require at least two years for completion and the supplemental application should include such a research plan and projected budget sheets. While not encouraged, a one-year application may be acceptable with appropriate justification. No new supplemental applications will be accepted in the final year of the current award.

V. FUNDING

Funding will be provided in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis. Continuing support for the second (or subsequent) year will depend upon approval of a satisfactory annual progress report and proposed budget from the minority investigator submitted with the principal investigator's non-competing continuation application. Funding for the supplement is always contingent on funding of the parent grant. Each supplemental budget shall not exceed \$25,000 in direct costs and may not include equipment. Supplemental awards made under this program are for the sole purpose of facilitating participation by minority investigators as described above.

VI. HOW TO APPLY

The principal investigator should submit a supplemental grant application through the institution on the Standard Form PHS 398, limited to the following: (1) Face page, at the top of which the applicant must designate the grant number of the active grant and specifically state "**Minority Investigator Supplement**" (For example, grant number **AI-12345-01 "Minority Research Enhancement Program"**); (2) budget page; (3) biographical sketch of the minority researcher; and (4) outline of the research project as it relates to the parent grant.

Applications received later than 90 days prior to a scheduled NAAID Council meeting may be reviewed at the subsequent NAAID Council meeting.

The original and four (4) copies of the application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please send two (2) copies to:

Dr. William E. Bennett
Chief, Research Manpower
Development Staff, EAP,
National Institute of Allergy
and Infectious Diseases
Westwood Building - Room 7A-03
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

THE NCI CLINICAL INVESTIGATOR AWARD

P.T. 34; K.W. 1200180, 1200270, 1002014

NATIONAL CANCER INSTITUTE

Application Receipt Dates: June 1, October 1, February 1

I. SUMMARY AND PURPOSE

The National Cancer Institute (NCI) announces the availability of Clinical Investigator Awards for the purpose of developing physician-researchers in basic and applied cancer sciences. The initiation of this award is intended to encourage recently-trained highly-qualified physicians (M.D. or D.O.) to undertake careers in cancer research. The award is prompted by the chronic shortage of physician-investigators, particularly surgical oncologists, therapeutic radiologists, diagnostic radiologist, preventive oncologists, physiatrists, nutritionists and epidemiologists. It is expected to facilitate the awardee's transition to independent basic or applied research. This three to five year award will enable successful candidates to investigate from three to five years of defined cancer problem under the guidance of an active researcher(s) who has the knowledge, background and research experience required to be a mentor in that field.

II. ELIGIBILITY

A. Candidate

The award is designed to provide intensive, supervised research experience primarily for those holding only a medical doctorate. Applications will be accepted from M.D.s or D.O.s holding the Ph.D or an equivalent degree. These applications will receive case by case consideration of special circumstances, such as a Ph.D. in unrelated field or an intervening period of clinical training since the completion of the Ph.D.

This program is described in the Catalog of Federal Domestic Assistance No. 13.398, Cancer Research Manpower. Award will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241 and administered under PHS grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 Clearinghouse or Health Systems Agency review.

- o Generally a person must have more than two years, and less than seven years, of postdoctoral experience at the time of application. Candidates not meeting this requirement must include in the application a strong justification for an exception.
- o A person who is or has been principal investigator on any NIH research grant or cooperative agreement or research and development contract or is or has been program director of a program project is not eligible to apply for a Clinical Investigator Award.

Candidates should have broad clinical training, demonstrate individual competence in clinical activities, and show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for engaging in research and/or academic careers. Only United States citizens, nationals or people admitted as permanent residents may be presented as candidates for this award.

B. Institution

The sponsoring institution must have a strong, well-established research program in the candidate's area of interest, and experienced faculty members in the clinical and basic departments relevant to the candidate's proposed training. The institution must include a plan for the candidate's research and academic development. Only domestic institutions are eligible.

C. Preceptor

The candidate's primary preceptor must be a competent investigator in the area of the candidate's proposed research activity. The preceptor must be active currently as an investigator, and prepared to provide personally much of the candidate's research supervision. The award is intended to provide an intensive, supervised research experience for the successful candidate.

III. PROVISIONS OF THE AWARD

The Clinical Investigator Award is made for a minimum period of three years and a maximum of five years. The award is nonrenewable and nontransferable. Support is based upon a full-time, twelve-month appointment. The award will provide salary support not to exceed \$40,000 annually from NCI funds. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience, and rank. This salary may be supplemented by the grantee institution in conformance with PHS policy. Up to a total of \$10,000 annually will be provided in years 01 and 02, and up to \$20,000 annually in new succeeding years for supplies, equipment, travel, etc., necessary for pursuit of the awardee's research program. Funds will be provided for the reimbursement of indirect cost at a rate not to exceed eight percent of the total allowable direct costs. When requested, the grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the employee's salary provided by the NCI Clinical Investigator Award.

It is expected that the candidate will spend at least 75 percent of his/her time in research during the period, with the remaining 25 percent being divided among other activities such as teaching, clinical training directly related to the research projects and course work. An appropriate sponsor must assume responsibility and provide guidance for the research development in the chosen areas.

Institutions may apply for awards on behalf of named individuals meeting the above criteria. It is not essential for the applicant institution to commit itself in the application to eventual placement of the candidate on its permanent, full-time faculty. However, it is expected that institutions will choose candidates of such caliber that they could meet the criteria for selection to such an appointment. Evidence of commitment to the candidate's research development must be provided by the institution.

Candidates for this award may not concurrently apply for a Research Career Development Award, an Academic Award or a New Investigator Research Award. The recipient of an NCI Clinical Investigator Award may apply for research grants during the term of his/her Clinical Investigator Award.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation and potential for an academic or research career. Candidates must have one or more sponsors at the institution who are recognized as accomplished researchers or teachers in the candidate's area of proposed development. The sponsor(s) must provide (1) his/her concept of a development and research plan for the candidates; (2) his/her updated curriculum vitae with a complete bibliography and research support; and (3) a letter indicating willingness to provide guidance and support for the award's duration.

Candidates must provide a full description of the proposed research and career development plan for the full period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award.

Candidates must agree to inform the NCI annually for a period of ten years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. REVIEW CRITERIA

Applications will undergo initial merit review in the Grants Review Branch, Division of Extramural Activities, NCI. Secondary review will be by the National Cancer Advisory Board. Criteria for review include:

- o The candidate's potential for a career in independent research.
- o The candidate's commitment to a research career.
- o The overall merit of the candidate's plan for research and the development of research skills.
- o The quality of the candidate's clinical training and experience.
- o The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development.

- o Presence of highly trained faculty in clinical and basic science departments relative to the area of study.
- o The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

V. HOW TO APPLY

Please read a copy of the "Program Guidelines" before applying for one of these awards. These are obtainable from the Program Director. An application for this award should be made on form PHS 398 (Rev. 5/82). The name of the program announcement should be typed in Section 2 on the face page of the application form. Application receipt dates are: February 1, June 1, and October 1.

This announcement and the program guidelines mentioned above are effective for all K08 applications reviewed by NCI for the June 1, 1985 and later receipt dates.

Please send two complete copies of the application to:

Referral Officer
Grants Review Branch
Division of Extramural Activities
National Cancer Institute
2115 East Jefferson Street - Room 401
Rockville, Maryland 20852

The original and four (4) copies should be sent to the Division of Research Grants as indicated in the instructions furnished in the application kit. Questions should be addressed to:

Program Director
Clinical Investigator Awards
Division of Cancer Prevention and Control
Blair Building - Room 424
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8898

ANNOUNCEMENT

RESEARCH AND DEMONSTRATIONS RELATING TO OCCUPATIONAL SAFETY AND HEALTH

P.T. 34, 12; K.W. 0701034

CENTERS FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

The Centers for Disease Control (CDC), National Institute for Occupational Safety and Health (NIOSH) announces that competitive grant applications are being accepted for research and demonstrations relating to occupational safety and health. These include innovative methods, techniques, and approaches for dealing with occupational safety and health problems in general industry and in the mining industry.

Support in the form of project grants will be awarded for annual budget periods, within a project period not to exceed five years.

I. AUTHORITY

These grants will be awarded and administered by NIOSH under the research and demonstration grant authority of Section 20(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1) and Section 501) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951). Program Regulations applicable to these grants are contained in Part 87 of Title 42, Code of Federal Regulations, "National Institute for Occupational Safety and Health Research and Demonstration Grants." Except as otherwise indicated, the basic grant administration policies of the Department of Health and Human Services and the Public Health Service are applicable to this program.

II. ELIGIBLE APPLICANTS

Eligible applicants include non-profit and for-profit organizations. Thus universities, colleges, research institutions and other public and private organizations including State and local governments and small, minority and/or woman-owned businesses are eligible for these research and demonstration grants. For-profit organizations will be required to submit a certification as to their status as part of their application.

III. PROGRAM REQUIREMENTS

A. Research Project Grants

A research project grant application should be intended and designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for dealing with occupational safety and health problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of underlying causes and mechanisms.

B. Demonstration Grants

A demonstration grant application should address, either on a pilot or full-scale basis, the technical or economic feasibility or application of: (1) a new or improved occupational safety or health procedure, method, technique, or system, or (2) an innovative method, technique, or approach for preventing occupational safety or health problems.

C. Special Emphasis Research Career Award (SERCA) Grants

The SERCA is designed to enhance the research capability of individuals in the formative stages of their careers who have demonstrated outstanding potential for contributing as independent investigators to health-related research. Candidates must have had two or more years of relevant postdoctoral experience prior to the submission date. The application must document accomplishments in this period that demonstrate research potential; it must also present a plan for additional experience in a productive scientific environment at domestic institutions that will foster development of a career of independent research in the area of occupational safety and health. The SERCA is not intended for untried investigators, or for productive, independent investigators with significant numbers of publications of high quality, or for persons of senior academic rank (above associate professor or tenured). Moreover, the award is not intended to substitute one source of salary support for another for an individual who is already conducting full-time research, nor is it intended to be a mechanism for providing institutional support. The application must demonstrate that the award will make a difference in and enhance the candidate's development as an independent investigator.

Candidates must indicate a commitment of at least 60 percent time (not necessarily 60% salary) devoted to research under the SERCA grant, although full-time is desirable. Other work in the area of occupational safety and health will enhance the candidate's qualifications but is not a substitute for this requirement. While working closely with the advisor(s), the awardee is expected to develop capabilities in fundamental, applied, and/or clinical research in one of the areas in section IV. At the end of the award period, evidence of independent investigative capability should be present such that the individual is better able to compete in traditional NIOSH research grant activities.

The total grant award may comprise direct costs of up to \$30,000 per year and up to eight percent additional indirect costs. Direct costs may include salary plus fringe benefits, technical assistance, equipment, supplies, consultant costs, domestic travel, publication, and other costs. If the awardee already holds a small grant on the same research topic, the amount of the SERCA may be reduced up to the amount of the small grant. Awards may be up to three years and will not be renewable.

D. Small Grants

A small grant application is intended to provide financial support to carry out exploratory or pilot studies, to develop or test new techniques or methods, or to analyze data previously collected. This small grant program is intended for predoctoral graduate students, post-doctoral researchers (within three years following completion of doctoral degree or completion of residency or public health training) and junior faculty members (no higher than assistant professor). If university policy requires that a more senior person be listed as principal investigator, the application should specify that the funds are for the use of a particular student or junior-level person and should include appropriate justification for this arrangement. Though biographical sketches are required only for the person actually doing the work, the application should indicate who would be supervising the research. Small grant applications should be identified as such on the application form.

The total small grant award may comprise direct costs of up to \$15,000 per year and additional indirect costs, as appropriate. The grants may be awarded for up to two years and are thereafter continuable by competitive renewal as a regular research grant. Salary of the principal investigator as well as that of the junior investigator, if university policy requires a senior person to be listed as the principal investigator, will not be allowed on a small grant, though salaries can be requested for necessary support staff such as laboratory technicians, interviewers, etc.

E. Program Project Grants

NIOSH will also accept applications for program project grants, but only after discussion with the individuals listed in this announcement.

IV. PROGRAMMATIC INTEREST

Examples of work-related programmatic interest to NIOSH which are applicable to all of the above types of grants are:

1. Occupational lung disease: asbestosis, byssinosis, silicosis, coal workers' pneumoconiosis, lung cancer, occupational asthma*
2. Musculoskeletal injuries: disorders of the back, trunk, upper extremity, neck, lower extremity: traumatically induced Raynaud's phenomenon*
3. Occupational cancers (other than lung): leukemia; mesothelioma; cancers of the bladder, nose and liver*
4. Amputations, fractures: eye loss, lacerations, and traumatic deaths*
5. Cardiovascular diseases: hypertension, coronary artery disease, acute myocardial infarction*
6. Disorders of reproduction: infertility, spontaneous abortion, teratogenesis*
7. Neurotoxic disorders: peripheral neuropathy, toxic encephalitis, psychoses, extreme personality changes (exposure-related)*

8. Noise-induced loss of hearing*
9. Dermatologic conditions: dermatoses, burns (scalding), chemical burns, contusions (abrasions)*
10. Psychologic disorders: neuroses, personality disorders, alcoholism, drug dependency*
11. Control technology research: application of scientific principles to control strategies; preconstruction review; technology forcing/new source performance concepts; technology transfer; substitution; unit operations approaches*
12. Respirator research: new and innovative respiratory protective devices; techniques to predict performance; effectiveness of respirator programs; physiologic and ergonomic factors; medical surveillance strategies; psychological and motivational aspects; effectiveness of sorbents and filters, including chemical and physical properties*

*The conditions or examples listed under each category are to be viewed as selected examples, not comprehensive definitions of the category. It should be noted, however, that investigators may apply in any areas related to occupational safety and health. Applications responding to this announcement will be reviewed by staff for their responsiveness and relevance to occupational safety and health. Assignment for program responsibility and funding will be according to established referral guidelines. Potential applicants with questions concerning the acceptability of their proposed work should contact the individuals listed in this announcement.

V. CRITERIA FOR REVIEW

Applications will be evaluated by a dual review process. The primary (peer) review is based on scientific merit and significance of the project, competence of the proposed staff in relation to the type of research involved, feasibility of the project, likelihood of its producing meaningful results, appropriateness of the proposed project period, adequacy of the applicant's resources available for the project, and appropriateness of the budget request.

Demonstration grant applications will be reviewed additionally on the basis of the following criteria:

- o Degree to which project objectives are clearly established, obtainable, and for which progress toward attainment can and will be measured.
- o Availability, adequacy, and competence of personnel, facilities, and other resources needed to carry out the project.
- o Degree to which the project can be expected to yield or demonstrate results that will be useful and desirable on a national or regional basis.
- o Extent of cooperation expected from industry, unions, or other participants in the project, where applicable.

SERCA grant applications will be reviewed additionally on the basis of the following criteria:

- o The review process will consider the applicant's scientific achievements, evidence of demonstrated commitment to a research career in occupational safety and health, and supportive nature of the research environment (including letter(s) of reference from advisor(s) which should accompany the application).

Small grant applications will be reviewed additionally on the basis of the following criteria:

- o The review process will take into consideration the fact that the applicants do not have extensive experience with the grant process.

A secondary review will also be conducted. Factors considered in the secondary review will include:

- o The results of the initial review.
- o The significance of the proposed study to the research programs of NIOSH.
- o National needs and program balance.
- o Policy and budgetary considerations.

VI. APPLICATION AND AWARD

Applications should be submitted on Form PHS-398 (revised May 1982) or PHS-5161-1 for State and local government applications. Forms should be available from the institutional business offices or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

The original and six copies of the application must be submitted to the address below on or before the specified receipt dates in accordance with the instructions in the PHS-398 packet:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In developing the application please note that the conventional presentation for grant applications should be used and the points identified under "CRITERIA FOR REVIEW" must be fulfilled.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application that are made available to outside reviewing groups. If the applicant's organization elects to exercise this option, use asterisks on the original and six copies of the application to indicate those individuals for whom salaries and fringe benefits are being requested; the subtotals must still be shown. In addition, submit an additional copy of page four of Form PHS-398, completed in full with the asterisks replaced by the amount of the salary and fringe benefits requested for each individual listed. This budget page will be reserved for internal PHS staff use only.

The instructions in the Form PHS-398 packet should be followed concerning deadlines for either delivering or mailing the applications. The application should be sent or delivered using the mailing label in the Form PHS-398 packet.

The proposed timetable for receiving applications and awarding grants is as follows:

All Except SERCA Grants and Small Grants

<u>Application Deadline</u>	<u>Primary Review Group Meeting</u>	<u>Secondary Review Meeting</u>	<u>Expected Start Date</u>
March 1	June	September	December 1
July 1	Oct./Nov.	January	April 1
November 1	Feb./Mar.	May	July 1

SERCA Grants and Small Grants

February 1	June	September	December 1
June 1	Oct./Nov.	January	April 1
October 1	Feb./Mar.	May	July 1

Awards will be made based on priority score ranking and emphasis area, as well as availability of funds.

VII. COST SHARING

Grantees will be expected to cost share a minimum of five percent.

VIII. FOR TECHNICAL INFORMATION CONTACT:

Roy M. Fleming, Sc.D.
Chief, Grants Administration and Review Branch
National Institute for Occupational Safety
and Health
Centers for Disease Control
1600 Clifton Road, N.E.
Building 1 - Room 3053
Atlanta, Georgia 30333

Telephone: (404) 329-3343

FOR BUSINESS INFORMATION CONTACT:

Leo A. Sanders
Grants Management Officer
Centers for Disease Control
255 E. Paces Ferry Road, N.E., Room 107A
Atlanta, Georgia 30305

Telephone: (404) 262-6575

(This program is described in the Catalog of Federal Domestic Assistance Program No. 13.262, Occupational Safety and Health Research Grants. It is not subject to Health Systems Agency nor Executive Order 12372 review.)

ANNOUNCEMENT

THE OLDEST OLD

P.T. 34; K.W. 0404002, 0701013, 0413001, 0408006, 0701016, 0701010, 1201230

THE NATIONAL INSTITUTE ON AGING

I. BACKGROUND AND GOALS

The National Institute on Aging (NIA) invites qualified researchers to submit new and supplemental applications for research projects which focus on the oldest old--those over age 85. Although the over age 85 population is still small in absolute numbers (about 2.6 million), it is forecast to be the fastest growing segment of the population for the period 1980-1990. For the last several decades the over age 85 population has been growing at almost three times the rate of that of all persons over age 65. While comprising only one percent of the total U.S. population today, this segment is projected to rise to 1.9 percent (5 million) by the year 2000, and 5.2 percent by 2050 (16 million). Assumptions about the future direction of the mortality rates of this age group powerfully influence these projections.

The oldest old are very substantial users of health care and other services. While about 6 percent of those aged 75-84 are institutionalized, the rate for those over age 85 is about 23 percent. The 1979 National Health Interview Survey data showed that in just the non-institutionalized elderly, the need for help from another person in one or more activities of daily living increased substantially. Seven percent of those aged 65-74 required help as compared to 16 percent for those aged 75-84, and to over 40 percent for those over 85. This gradient was even steeper in the female population, which greatly outnumbers the male population at older ages. If the current utilization rates for health and other services for this age group are extrapolated simply as a function of the projected growth of the oldest old population, then the implications for society are considerable.

The Federal Government provides, by some estimates, \$51 billion in major benefits to those 80 and over. Yet, at almost all levels, from the demographic to the physiologic, less is known about this age group than about any other. For example, federal statistics rarely provide detailed information on those over age 85. Our lack of knowledge about the oldest old results from a number of factors. Until recently their absolute numbers have been small, the available data have often been perceived to be of low quality, and this age group has been considered difficult to study.

This program is described in the Catalog of Federal Domestic Assistance No.13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66, and Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

This announcement of NIA's special initiative on the Oldest Old supplements, but does not replace, such prior announcements as "Social and Behavioral Research" and "Health and Effective Functioning in the Middle and Later Years".¹ This initiative is being sponsored jointly by the Behavioral Sciences Research and Biomedical Research and Clinical Medicine Programs of the NIA, and is coordinated with related programs in the National Institute of Mental Health and the National Institute of Child Health and Human Development.

II. SPECIFIC OBJECTIVES

This announcement indicates the wide array of knowledge needed, starting with the urgently needed assessment of the quality of the existing data, and the development of improved sources of information and methodologies for studying the oldest old. Also needed are descriptive and analytic studies. Among the broad topics of concern are:

A. Assessment of Existing Data and Methodological Innovations

1. Studies assessing the quality of existing data, and methodological innovations to improve data quality; e.g.:
 - o Studies which improve the representativeness and reliability of data for those over 85, including studies to sharpen current definitions of the household by delineating new types of living arrangements. Improved methods for interviewing and obtaining valid and reliable data for persons with limitations of hearing, vision, memory or comprehension. Improved methods of collecting data in institutions; analyses of the differences in the quality of data collected from the individual versus that from administrative records or from proxy respondents. Studies leading to improved record collecting, cause-of-death reporting, and an increased autopsy rate. Studies which improve the measurement of the various forms of functional ability.
 - o Studies to improve the ability to project and forecast changes in life expectancy and active life expectancy. Development of improved methods for assigning confidence bands to projection.

B. General Characteristics of the Oldest Old

1. Socio-demographic studies within both the United States and other industrialized nations such as:
 - o Distribution and projections by, e.g., sex, race, education, income, residence, and living arrangements. Investigations of migration. Analyses of the composition and proximity of surviving kin.

¹/ See NIH Guide for Grants and Contracts, Vol. 12, No. 6, June 17, 1983, pp.5-15, Vol. 10, No. 10, September 4, 1981.

- o Analyses of sociodemographic historical trends in the oldest old, and the impact of cohort succession (e.g., in the percent foreign born and of increasing levels of education, etc.) on their characteristics.
 - o Economic issues such as the distribution of income and wealth in sub-populations, and the conditions under which financial reserves become exhausted; the impact of anticipated institutionalization on saving and consumption; the transmission of assets and patterns of exchange between generations; illiquidity and the implications of reverse mortgages; the assessment of income adequacy measures; relationships between financial status and sense of financial well-being; conditions of daily life of those below, or close to, the poverty line; the economic determinants of living arrangements.
2. Descriptions and analyses of patterns of functioning, morbidity, and disease-specific causes of death. For example:
- o Studies of stability and decline in such abilities as memory and problem solving; individual reactions to reduced competency; the epidemiology of sensory and communication problems.
 - o Clinical, pathologic, and epidemiological data on the prevalence, course, morbidity, and mortality of diseases.
 - o Physiologic factors (e.g., metabolic, endocrine, immune, skeletal-muscular, sensory, and cardiovascular) which increase or diminish risk for decrements in functioning, specific diseases, and mortality from disease.
 - o The interaction of multiple disease processes to determine the effects of co-existent diseases on functioning, morbidity, mortality, and implications for intervention and therapy.
 - o Studies of variation in mortality, morbidity, and patterns of functioning among the population sub-groups of the oldest old within the U.S. and other nations. Studies of the reported "mortality cross-over" phenomenon between black elderly and their white counterparts. Factors which may be associated with differential survival, health, and functioning at the oldest ages, including lifestyle, health behaviors, medical and self care, and genetic and familial background.

C. Interactions with the Society Including Care Systems

1. Studies of the care systems of the oldest old in areas such as:
- o The impact of the changing family and increasing participation of women in the labor force on the provision of care for future cohorts of the oldest old. Social and economic effects on families caring for the frail oldest old. The impact of health care reimbursement policies on relationships between formal and informal care systems. Assessment of the resources which allow

functioning outside of long-term care settings.

- o Studies of the last year of life including interactions among patients, family, care providers, nursing homes, and the legal system, and implications for costs and patient well-being.
2. Factors affecting institutionalization and use of services, e.g.:
 - o Dementia and other cognitive impairments; osteoarthritis and other causes of impaired mobility; falls and other injuries; and urinary and fecal incontinence.
 - o Living arrangements and the physical characteristics of housing units, including innovations designed to keep the frail in the community, and the availability of support. Comparative analyses among jurisdictions, social, ethnic, and racial groups, or other nations with different rates of institutionalization.
 3. Interactions between the oldest old population and society, e.g.:
 - o Forecasting and modeling the impact of the rapid growth of the oldest old population on e.g., the economy, the social security system, the insurance industry, the distribution of income, the health care system, housing, the political system, intergenerational solidarity; and the family structure. Dynamics of resource allocation among age strata. Comparisons of the adaptation of institutions to the growth of the over 85 population across industrialized nations experiencing different rates of structural aging. The impact of social trends.
 - o Special socio-legal problems of this age category; comparison among jurisdictions in the United States of the impact of laws (and their changes) affecting the oldest old and their families; studies of their interactions with the legal system, including analyses of conservatorships, the right of patients to refuse or terminate care and the reactions of institutions to such requests.

III. METHODOLOGY

Research applications need not be limited to any particular methodology of data collection or analysis. Designs will frequently need to include comparisons with age groups below age 85. Designs may include demographic, epidemiological, econometric, and clinical studies with cross-sectional, longitudinal, or cohort designs. Cross-national (and multi-state) comparisons are strongly encouraged. Secondary analysis of existing data is encouraged, although collection of new data will be necessary to meet particular objectives. Where new data are collected, very careful consideration should be given to human subject concerns (see NIH Guide for Grants and Contracts, Vol. 10, No. 4, March 6, 1981).

IV. APPLICATION SUBMISSION AND REVIEW

Applications received in response to this announcement will be assigned to regular peer review groups and will be considered in accordance with NIH guidelines.

Interest in some of the above areas is shared by the National Institute of Mental Health (NIMH). Applications will be assigned according to standing referral guidelines. Information on NIMH program interests can be obtained from;

Center for Studies of the Mental Health
of the Aging
Parklawn Building - Room 11C-03
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1185.

The review criteria are the traditional considerations underlying scientific merit.

Investigators are encouraged to discuss their projects and the range of available grant mechanisms with NIA staff in advance of formal submission. This can be done through a telephone conversation or brief (4-5 page) research prospectus. Applicants should use the regular research project application form (PHS 398), which is available at the applicant's institutional Application Control Office or from:

Office of Grants Inquiries
Division of Research Grants (DRG)
National Institutes of Health

Telephone: (301) 496-7441

In order to expedite the routing of applications within NIH, please (1) check the box on the application face sheet indicating that your proposal is in response to this announcement and print (next to the checked box) "NIA: THE OLDEST OLD" and (2) enclose a cover letter repeating that your application is in response to this announcement.

Mail the cover letter and the completed application (with 6 copies) to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Receipt dates for Research Project Grant and New Investigator Award applications are: March 1, July 1, and November 1; for others, including Postdoctoral Fellow and Program Project applications: February 1, June 1, October 1.

Address requests for additional information (e.g., sources of data) research prospectuses, and/or letters of intent to:

For all topics other than biomedical:

National Institute on Aging
Behavioral Sciences Research
Attention: "Oldest Old"
Building 31C - Room 4C32
Bethesda, Maryland 20205

Telephone: (301) 496-3136

For biomedical topics:

National Institute on Aging
Biomedical Research and
Clinical Medicine
Attention: "Oldest Old"
Building 31C - Room 5C21
Bethesda, Maryland 20205

Telephone: (301) 496-1033



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